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UNITED STATES PATENT AND TRADEMARK
BEFORE THE PATENT TRIAL AND APPEAL BOARD

- - - - - x
HOPEWELL PHARMA VENTURES, :
INC., : Case IPR2023-00480
Petitioner, : (Patent 7,713,947 B2)
v. :
MERCK SERONO S.A., : Case IPR2023-00481
Patent Owner. : (Patent 8,377,903 B2)

- - - - - x

*** CONFIDENTIAL ***

Videotaped Deposition of:
YOGESH DANDIKER, Ph.D.
Minneapolis, MN
Friday, February 16, 2024
9:41 a.m.

Reported Stenographically By:
Amy L. Larson, RPR, CCR, CSR
Job No. 524917

CONFIDENTIAL
Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

2

1 Videotaped Deposition of YOGESH DANDIKER, Ph.D.,
2 held at the office of:

3
4 Fabyanske, Westra, Hart & Thomson, P.A.,
5 333 South Seventh Street
6 Suite 2600
7 Minneapolis, MN 55402

8
9 Pursuant to Notice, before Amy L. Larson,
10 Registered Professional Reporter, Certified
11 Court Reporter, Certified Shorthand Reporter, and
12 Notary Public in and for the State of Minnesota.

CONFIDENTIAL
Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

3

A P P E A R A N C E S:

ON BEHALF OF THE PETITIONER:

TYLER C. LIU, ESQUIRE (via Zoom)

ELDORA L. ELLISON, Ph.D., ESQUIRE (via Zoom)

OLGA A. PARTINGTON, Ph.D., ESQUIRE (via Zoom)

CHRISTINE E. DASHE, ESQUIRE (via Zoom)

MADELEINE BOND, ESQUIRE

STERNE KESSLER GOLDSTEIN & FOX, PLLC

1101 K. Street NW

10th Floor

Washington, DC 20005

ON BEHALF OF THE PATENT OWNER:

MARY PHENG, ESQUIRE

ASHER MCGUFFIN, ESQUIRE (Boston) (Via Zoom)

WILMER CUTLER PICKERING HALE AND DORR, LLP

7 World Trade Center

250 Greenwich Street

New York, New York 10007

1 ALSO PRESENT:

2 WILLEM F.C. de WEERD,

3 Corporate Patent Counsel, Merck

4 Malcolm Cooke, Videographer

5 Rachel Carrick, Technician

6

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Transcript of Yogesh Dandiker, Ph.D.
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1 INDEX:

2 EXAMINATION BY: PAGE

3 Mr. Liu 8

4 Ms. Pheng 219

5 EXHIBITS REFERENCED:

6 Exhibit No.

7 1022 88
8 PCT

9 1057 116
10 Transmittal Letter

11 1058 104
12 Request for Filing Continuation

13 2029 100
14 US Patent No. 8,785,415

15 2049 179
16 Briefing Document

17 2050 125
18 Meeting Minutes

19 2055 18
20 Dandiker Declaration

21 2069 111
22 US Patent No. 7,888,328

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	P R O C E E D I N G S	
2	THE TECHNICIAN: Thank you to	09:41:56
3	everyone for attending this proceeding	09:41:57
4	remotely, which we anticipate will run	09:41:58
5	smoothly.	09:42:02
6	Please remember to speak slowly and	09:42:03
7	do your best not to talk over one another.	09:42:05
8	Please be aware that we are recording this	09:42:07
9	proceeding for backup purposes. Any	09:42:09
10	off-the-record discussion should be had away	09:42:12
11	from the computer. Please remember to mute	09:42:14
12	your mic for those conversations.	09:42:16
13	Please have your video enabled to	09:42:19
14	help the reporter identify who is speaking.	09:42:21
15	If you are unable to connect with video and	09:42:24
16	are connecting via phone, please identify	09:42:26
17	yourself each time before speaking.	09:42:29
18	I apologize in advance for any	09:42:31
19	technical-related interruptions.	09:42:33
20	Thank you.	09:42:36
21	THE VIDEOGRAPHER: Here begins	09:42:38
22	Media Number 1 in the videotaped deposition	09:42:40

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1 of Dr. Yogesh Dandiker in the matter of
2 Hopewell Pharma Ventures, Inc. v.
3 Merck Serono S.A., PTAB, in the United States
4 Patent and Trademark Office, Before the
5 Patent Trial and Appeal Board, IPR2023-00480
6 and IPR2023-00481.

09:42:42

09:42:47

09:42:49

09:42:54

09:42:56

09:43:04

7 The remote [sic] videographer today
8 is Malcolm Cooke representing Planet Depos.
9 Some parties of this video deposition are
10 attending remotely. The witness is located
11 at 333 South Seventh Street, Suite 2600,
12 Minneapolis, Minnesota 55402.

09:43:10

09:43:11

09:43:15

09:43:17

09:43:21

09:43:27

13 The remote -- the court reporter
14 today -- or would counsel please voice
15 identify themselves and state whom they
16 represent.

09:43:31

09:43:33

09:43:36

09:43:38

17 MR. LIU: Sure. My name is
18 Tyler Liu, from Sterne Kessler, on behalf of
19 Petitioner Hopewell.

09:43:40

09:43:42

09:43:45

20 With me today remotely are
21 Eldora Ellison, Olga Partington, and

09:43:45

09:43:47

22 Christina Dashe, also of Sterne Kessler.

09:43:51

CONFIDENTIAL
Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	With me today in person with the	09:43:54
2	witness is Madeleine Bond also of	09:43:56
3	Sterne Kessler.	09:43:58
4	MS. PHENG: Good morning. My name	09:43:59
5	is Mary Pheng of WilmerHale, representing	09:44:01
6	patent owner. With me remotely is	09:44:03
7	Asher McGuffin, also of WilmerHale, and	09:44:06
8	Willem de Weerd of Merck Serono.	09:44:09
9	THE VIDEOGRAPHER: The court	09:44:12
10	reporter today is Amy Larson representing	09:44:12
11	Planet Depos. The witness will now be sworn.	09:44:15
12		
13	YOGESH DANDIKER, Ph.D.,	
14	after having been first duly sworn to	
15	tell the truth, the whole truth and	
16	nothing but the truth, was examined and	
17	testified as follows:	
18		
19	EXAMINATION	09:44:28
20	BY MR. LIU:	09:44:28
21	Q. Good morning, Mr. Dandiker. Can you please	09:44:29
22	state and spell your name for the record.	09:44:32

CONFIDENTIAL
Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	A. Yeah. It's Yogesh Dandiker, Y-O-G-E-S-H,	09:44:34
2	D-A-N-D-I-K-E-R.	09:44:38
3	Q. Dr. Dandiker, have you ever been deposed	09:44:41
4	before?	09:44:44
5	A. Yes.	09:44:45
6	Q. Okay. How many times?	09:44:45
7	A. Twice before.	09:44:48
8	Q. And any of these depositions in a case or a	09:44:49
9	proceeding relating to patents?	09:44:54
10	A. Yes.	09:44:56
11	Q. And any depositions in a proceeding before	09:44:56
12	the Patent Office?	09:45:01
13	A. No.	09:45:04
14	Q. Okay. Let's go over some ground rules.	09:45:05
15	I'll be asking you some questions,	09:45:11
16	and your counsel may object. But it's	09:45:12
17	important for the court reporter that we	09:45:15
18	don't talk over each other.	09:45:17
19	Do you agree?	09:45:20
20	A. Yup.	09:45:20
21	Q. Similarly, the court reporter can't take down	09:45:21
22	nonverbal answers, like shaking your head or	09:45:25

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	saying "uh-huh." So can you agree to give	09:45:28
2	only verbal answers?	09:45:30
3	A. Yup. Sure.	09:45:31
4	Q. Okay. Sometimes your counsel may object to	09:45:33
5	my questions, but you still have to answer	09:45:37
6	them unless counsel directs you not to answer	09:45:39
7	them.	09:45:42
8	Will you agree to abide by this rule?	09:45:42
9	A. Yes.	09:45:45
10	Q. If at any point that you need a break, please	09:45:46
11	let me know and I will try to accommodate.	09:45:51
12	But I do ask that you answer any pending	09:45:53
13	questions before we take a break.	09:45:56
14	Will you agree to do that?	09:45:57
15	A. Yes.	09:45:58
16	Q. Now, if I ask you a question that you don't	09:45:58
17	understand or need further clarification,	09:46:03
18	will you agree to let me know and I can try	09:46:05
19	to clarify or ask a better question?	09:46:07
20	A. Yup.	09:46:10
21	Q. However, if you do answer my question, I'll	09:46:11
22	assume you have understood it.	09:46:15

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	Do you agree?	09:46:16
2	A. Yes.	09:46:18
3	Q. Because we are operating on a remote basis	09:46:19
4	today for this deposition, there may be some	09:46:24
5	technical difficulties. If anything happens	09:46:26
6	that interferes with your ability to	09:46:29
7	understand or answer my questions, will you	09:46:32
8	agree to let me know?	09:46:34
9	A. Yes.	09:46:36
10	Q. Now, during my questioning today, the	09:46:38
11	Patent Office rules require that you are not	09:46:42
12	permitted to discuss your testimony with	09:46:44
13	counsel unless you're discussing an issue	09:46:45
14	relating to privilege.	09:46:48
15	Will you agree to abide by this rule?	09:46:49
16	A. Yeah.	09:46:51
17	Q. Dr. Dandiker, is there any reason you can't	09:46:55
18	give truthful testimony today?	09:46:58
19	A. No.	09:47:01
20	Q. Okay. Dr. Dandiker, where are you located	09:47:01
21	today?	09:47:06
22	A. In Minneapolis.	09:47:06

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	Q. Is there anyone else in the room besides	09:47:10
2	counsel, the court reporter and the	09:47:12
3	videographer?	09:47:14
4	A. I think, obviously, the counsel from your	09:47:18
5	side, as well as the court reporters.	09:47:21
6	Q. Okay. Whose computer are you using for	09:47:25
7	today's deposition?	09:47:30
8	A. I don't know.	09:47:30
9	Q. Sorry, can you say that again?	09:47:32
10	A. I don't know whose computer it is, actually.	09:47:34
11	Q. Okay. So it's not your computer, correct?	09:47:36
12	A. It's not my computer.	09:47:39
13	Q. Sorry, you're going to have to say that one	09:47:41
14	more time.	09:47:44
15	A. No, it's not my computer. I don't know whose	09:47:44
16	it is.	09:47:47
17	Q. Do you have any files or programs open on	09:47:47
18	your computer besides the deposition video	09:47:50
19	platform?	09:47:53
20	A. No.	09:47:53
21	Q. Okay. Do you have access to any files or	09:47:55
22	programs on your computer today besides the	09:48:00

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	deposition video platform?	09:48:03
2	A. No. I mean, it's not my computer, so I don't	09:48:05
3	have access.	09:48:09
4	Q. And do you agree not to access any documents,	09:48:10
5	PDFs, emails, web browsers, including on any	09:48:13
6	breaks?	09:48:17
7	A. Yes, yes.	09:48:17
8	Q. Do you have any other electronic devices with	09:48:23
9	you today?	09:48:27
10	A. Yeah, I have my cell phone.	09:48:28
11	Q. And where is that cell phone?	09:48:29
12	A. It's on the table next to me.	09:48:32
13	Q. Okay. And you would agree that you won't be	09:48:36
14	accessing your cell phone today during this	09:48:38
15	deposition?	09:48:40
16	A. Yes.	09:48:40
17	Q. Okay. Dr. Dandiker, did you bring anything	09:48:46
18	else with you today to your deposition?	09:48:48
19	A. My laptop.	09:48:51
20	Q. Okay. And you agree that you won't be	09:48:53
21	accessing your laptop, including on any	09:48:56
22	breaks, correct?	09:48:59

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

14

1	A. Yes.	09:49:00
2	Q. Okay. And is there anything in front of you	09:49:00
3	right now besides the laptop?	09:49:04
4	A. No. No, other than, you know, a glass of	09:49:07
5	water.	09:49:11
6	Q. Okay. Great.	09:49:13
7	Dr. Dandiker, when were you first	09:49:16
8	approached to provide testimony in these two	09:49:19
9	cases?	09:49:22
10	A. I think it's sometime, I would say, back end	09:49:24
11	of last year. I can't remember the exact	09:49:31
12	date.	09:49:32
13	Q. Was it before December of last year?	09:49:33
14	A. It could be. I mean, I was traveling and,	09:49:38
15	you know, that's when the first contact was	09:49:41
16	made.	09:49:45
17	Q. So you can't recall an exact date, but --	09:49:45
18	A. Yeah.	09:49:48
19	Q. -- it's around November, December time last	09:49:48
20	year?	09:49:51
21	A. Yeah. Yeah, so I just kind of -- I think I	09:49:51
22	was at an airport, and I just kind of	09:49:55

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	responded on my cell phone.	09:50:00
2	Q. Okay. And who were you approached by?	09:50:01
3	A. By a representative of WilmerHale.	09:50:11
4	Q. Okay. And do you remember this person's	09:50:16
5	name?	09:50:20
6	A. Deric, I think spelled with D-R -- D-E-R-I-C.	09:50:23
7	Q. Okay. Do you remember Deric's last name?	09:50:31
8	A. I can't recall at the moment.	09:50:40
9	Q. Okay. Dr. Dandiker, what did you do to	09:50:43
10	prepare for your deposition today?	09:50:46
11	A. I had some preparation with the counsel.	09:50:48
12	Q. And when did you have -- when did you meet	09:50:56
13	with counsel?	09:51:00
14	A. Yesterday.	09:51:01
15	Q. Did you meet with counsel any time before	09:51:01
16	yesterday in preparation for your deposition	09:51:06
17	today?	09:51:09
18	A. Yes, we had some interactions regarding my	09:51:09
19	declaration.	09:51:13
20	Q. And when was that?	09:51:15
21	A. That was, I would say, early part of the	09:51:17
22	year, or early -- or I would say back end of	09:51:21

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	last year and early part of this year.	09:51:25
2	Q. Okay. My question is a little different. I	09:51:27
3	was asking when did you meet.	09:51:31
4	Did you only meet with counsel	09:51:33
5	yesterday in preparation for your deposition	09:51:35
6	today?	09:51:37
7	A. In person, yes.	09:51:37
8	Q. Okay. And did you meet with counsel prior to	09:51:40
9	yesterday to prepare for your deposition	09:51:47
10	today?	09:51:48
11	A. In person, no. But remotely, yes.	09:51:50
12	Q. Okay. And how much time did you spend in	09:51:53
13	preparation for the deposition?	09:52:01
14	A. It's difficult to quantify. I mean, I would	09:52:05
15	say maybe a day, day and a half, two days.	09:52:13
16	Q. Do you recall how many hours per day you	09:52:25
17	spent in preparation for your deposition?	09:52:28
18	A. I would say all of yesterday. And in terms	09:52:32
19	of preparation, I would -- just to clarify,	09:52:40
20	would that also mean getting the	09:52:42
21	declaration -- my declaration together?	09:52:46
22	Would that be preparation?	09:52:48

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	I'm asking a question.	09:52:53
2	Q. My question is: Do you recall how many hours	09:52:56
3	per day you spent in preparation for your	09:52:59
4	deposition today?	09:53:01
5	A. Yeah, I'm asking for clarification. Would	09:53:02
6	that mean that preparing the declaration	09:53:05
7	would be part of that preparation?	09:53:08
8	Q. How much time did you spend after signing	09:53:12
9	your declaration in preparation for your	09:53:16
10	deposition?	09:53:19
11	A. Let's say two days.	09:53:21
12	Q. And would you say more or less than eight	09:53:22
13	hours per day?	09:53:27
14	A. Yes.	09:53:28
15	Q. And who did you meet with in preparation for	09:53:28
16	this deposition?	09:53:35
17	A. I met Mary Pheng yesterday.	09:53:38
18	Q. Anyone else?	09:53:41
19	A. From WilmerHale, yeah, I had a call with a	09:53:43
20	couple of other attorneys.	09:53:51
21	Q. Okay. Do you recall their names?	09:53:53
22	A. Yeah. Asher and Deric.	09:53:57

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1	Q. Did you meet with anyone else outside of	09:54:01
2	counsel for WilmerHale in preparation for	09:54:04
3	your deposition?	09:54:06
4	A. No.	09:54:07
5	Q. Dr. Dandiker, did you consider any documents	09:54:12
6	that are not cited in your declaration in	09:54:15
7	preparing for this deposition today?	09:54:18
8	A. No.	09:54:21
9	MR. LIU: Rachel, can we bring up	09:54:29
10	Tab 1, which should be Dr. Dandiker's	09:54:31
11	declaration.	09:54:36
12	THE TECHNICIAN: Please standby.	09:54:37
13	We're marking this as Exhibit 1?	09:54:39
14	MR. LIU: You don't have to mark	09:54:40
15	it. It's already been marked as	09:54:42
16	Exhibit 2055.	09:54:45
17	THE TECHNICIAN: Okay.	09:54:45
18	MS. PHENG: Tyler, I have a	09:54:46
19	physical copy, I think I mentioned this	09:54:48
20	previously, of Dr. Dandiker's declaration.	09:54:50
21	Madeleine has had an opportunity to inspect	09:54:53
22	it. If this is all right with you, I'd like	09:54:56

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	to hand him a physical copy so he has it.	09:54:58
2	MR. LIU: Okay. Sure.	09:54:58
3	And you confirm that there's no	09:55:03
4	markings of any kind on that declaration?	09:55:04
5	MS. BOND: Yes.	09:55:07
6	MR. LIU: Okay. Great. Thank	09:55:09
7	you.	09:55:17
8	BY MR. LIU:	09:55:17
9	Q. Dr. Dandiker, this is your declaration that	09:55:17
10	you submitted in cases IPR2023-00480 and	09:55:19
11	IPR2023-00481, correct?	09:55:24
12	A. Yup.	09:55:29
13	Q. Okay. Now, if I refer to this case, you will	09:55:29
14	understand that it collectively means both	09:55:34
15	IPR proceedings, correct?	09:55:37
16	A. Yes.	09:55:40
17	Q. Okay. Now, for purposes of my questions	09:55:40
18	today, I'm just going to refer to your	09:55:44
19	declaration from the '480 IPR.	09:55:47
20	Is that okay?	09:55:50
21	A. Yes.	09:55:51
22	Q. Okay. And I'm going to assume that any	09:55:54

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Transcript of Yogesh Dandiker, Ph.D.
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1	answers you provide will apply to your other	09:55:58
2	declaration in the '481 IPR.	09:56:00
3	Do you agree?	09:56:02
4	A. Yeah.	09:56:03
5	Q. Okay. Now, if we could go to page 13 of the	09:56:03
6	PDF.	09:56:09
7	A. All right.	09:56:14
8	Q. Let me know when you're there. Okay.	09:56:16
9	Dr. Dandiker, your declaration is	09:56:21
10	signed and dated on December 21st, 20 --	09:56:23
11	2023, correct?	09:56:27
12	A. Yes.	09:56:28
13	Q. And that is your signature on the page?	09:56:28
14	A. Yup.	09:56:31
15	Q. Dr. Dandiker, do you stand by your testimony	09:56:31
16	in your declaration in this case?	09:56:36
17	A. Yes.	09:56:38
18	MS. LIU: Okay, Rachel, you can	09:56:40
19	take it down.	09:56:42
20	THE TECHNICIAN: (Complies.)	09:56:43
21	BY MR. LIU:	09:56:44
22	Q. Dr. Dandiker, you were asked to provide this	09:56:44

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

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1	declaration as an inventor of the Bodor PCT	09:56:48
2	patent application titled, Oral Formulations	09:56:52
3	of Cladribine, correct?	09:56:54
4	A. Yes.	09:56:56
5	Q. Okay. Do you intend to supplement or revise	09:56:56
6	your testimony at any later date?	09:57:02
7	A. No.	09:57:05
8	Q. Dr. Dandiker, how long did you spend	09:57:06
9	preparing your declaration?	09:57:11
10	A. I would say, you know, two, three days.	09:57:19
11	Q. And how many hours per day?	09:57:23
12	A. Eight hours.	09:57:26
13	Q. Okay. Dr. Dandiker, do you know who else	09:57:28
14	provided testimony in this case?	09:57:33
15	A. I knew yesterday that Dr. Bodor did.	09:57:38
16	Q. And how did you know that Dr. Bodor provided	09:57:50
17	testimony in this case?	09:57:53
18	A. I heard a conversation that his deposition	09:57:54
19	was yesterday.	09:57:59
20	Q. And who did you have a conversation with?	09:58:01
21	A. I didn't have a conversation, per se, but I	09:58:05
22	think I overheard the attorneys talking that	09:58:08

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Transcript of Yogesh Dandiker, Ph.D.
Conducted on February 16, 2024

22

1	there was a declaration yesterday from	09:58:12
2	Dr. Bodor. Not a declaration, deposition.	09:58:15
3	Q. So you only heard that Dr. Bodor had a	09:58:21
4	deposition yesterday from counsel, correct?	09:58:26
5	A. Yeah, yeah.	09:58:28
6	Q. Did you speak with Dr. Bodor?	09:58:30
7	A. No.	09:58:32
8	Q. Did you review Dr. Bodor's deposition	09:58:40
9	transcript?	09:58:42
10	A. No.	09:58:43
11	Q. Did you discuss Dr. Bodor's deposition with	09:58:47
12	anyone in preparation for your deposition	09:58:50
13	today?	09:58:51
14	A. No.	09:58:54
15	Q. Are you aware of what was asked of Dr. Bodor	09:58:54
16	at his deposition?	09:58:57
17	A. No.	09:58:58
18	Q. Do you know who else provided testimony	09:59:11
19	besides Dr. Bodor in this case?	09:59:12
20	A. No, I don't.	09:59:17
21	Q. Have you read any testimony from any other	09:59:20
22	individuals in this case?	09:59:22

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1	A. No. No, I have not.	09:59:23
2	Q. Have you talked to anyone besides counsel	09:59:28
3	regarding the substance of your deposition	09:59:39
4	today?	09:59:41
5	A. I have not.	09:59:42
6	Q. I may have asked this earlier, but I just	09:59:49
7	want to clarify.	09:59:51
8	Do you know who else provided a	09:59:52
9	declaration in this case besides Dr. Bodor?	09:59:53
10	A. I don't.	09:59:56
11	Q. Besides counsel, did you communicate with	09:59:59
12	anyone else in order to create your	10:00:08
13	declaration?	10:00:12
14	A. No.	10:00:12
15	Q. Dr. Dandiker, are you familiar with	10:00:12
16	Dr. Alain Munafo? I'll spell it for you.	10:00:21
17	First name A-L-A-I-N, last name M-U-N-A-F-O.	10:00:24
18	A. Not recently. I was aware of Dr. Munafo when	10:00:30
19	I was at IVAX maybe 20 years ago.	10:00:42
20	Q. So you didn't speak with him in preparing	10:00:47
21	your declaration or for your deposition	10:00:49
22	today, correct?	10:00:50

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1	A. No, no. Yeah.	10:00:51
2	Q. Okay. And approximately when was the last	10:00:52
3	time you communicated with Dr. Munafo?	10:00:56
4	A. I would say maybe 20 years ago.	10:01:00
5	Q. And do you recall what that conversation with	10:01:10
6	Dr. Munafo was about?	10:01:12
7	A. No.	10:01:13
8	Q. How often did you communicate with Dr. Munafo	10:01:20
9	after you left IVAX?	10:01:23
10	A. I did not communicate at all.	10:01:26
11	Q. So the last time you communicated with	10:01:31
12	Dr. Munafo was around 2004; is that correct?	10:01:34
13	A. Yeah. Yes.	10:01:37
14	Q. Dr. Dandiker, have you heard of a	10:01:45
15	Dr. Bernd Meibohm? First name B-E-R-N-D,	10:01:48
16	last name M-E-I-B-O-H-M.	10:01:53
17	A. No, I can't recall.	10:01:58
18	Q. So you don't know a Dr. Meibohm, correct?	10:02:04
19	A. Yeah. Yes.	10:02:07
20	Q. Okay. Dr. Dandiker, have you heard of an	10:02:08
21	individual named Dr. Fred Luvlin? First name	10:02:14
22	F-R-E-D, last name L-U-V-L-I-N.	10:02:19

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1	A. No, I can't recall.	10:02:25
2	Q. Have you communicated with anyone who was	10:02:33
3	formerly employed at IVAX in preparing your	10:02:36
4	declaration?	10:02:39
5	A. No.	10:02:40
6	Q. Dr. Dandiker, are you familiar with an	10:02:46
7	individual named Dr. Stephen Marcus?	10:02:48
8	A. Yes.	10:02:52
9	Q. When was the last time you communicated with	10:02:52
10	Dr. Marcus?	10:02:58
11	A. It must have been 2004.	10:03:00
12	Q. So you didn't communicate with Dr. Marcus	10:03:04
13	after you left IVAX?	10:03:07
14	A. Yes, that's correct.	10:03:08
15	Q. Do you recall what you communicated with	10:03:10
16	Marcus -- Dr. Marcus 20 years ago?	10:03:13
17	A. No, I don't recall.	10:03:18
18	MR. LIU: Sorry, I'm hearing a	10:03:25
19	little bit of feedback.	10:03:26
20	THE VIDEOGRAPHER: Yeah, I believe	10:03:28
21	that might be the microphone rubbing against	10:03:29
22	somebody's lapel, so just make sure it's	10:03:32

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1	directed upward and try not to shift too	10:03:34
2	much.	10:03:41
3	MR. LIU: Okay. Great. Thank	10:03:41
4	you.	10:03:45
5	BY MR. LIU:	10:03:45
6	Q. Dr. Dandiker, what was Dr. Marcus's job title	10:03:46
7	at IVAX?	10:03:49
8	A. At the moment, I can't recall. I don't	10:03:49
9	remember what his title was.	10:03:52
10	Q. What was Dr. Marcus's role at IVAX?	10:04:01
11	MS. PHENG: Objection to form.	10:04:07
12	THE WITNESS: I can't recall. I	10:04:11
13	mean, I spoke to him about a lot of different	10:04:13
14	things, so I -- you know, I don't remember	10:04:17
15	specifically what his role was.	10:04:20
16	BY MR. LIU:	10:04:28
17	Q. So you don't recall what Dr. Marcus's role at	10:04:28
18	IVAX was?	10:04:31
19	A. Well, other than, you know, more specifically	10:04:34
20	being enrolled with the, you know, PK studies	10:04:40
21	for cladribine --	10:04:44
22	THE COURT REPORTER: I'm sorry,	10:04:45

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1	can you repeat that?	10:04:46
2	THE WITNESS: Yeah.	10:04:48
3	Pharmacokinetic studies. I -- other than	10:04:48
4	that, I just don't know what else he did.	10:04:51
5	BY MR. LIU:	10:04:54
6	Q. And what was Dr. Marcus's role with respect	10:04:56
7	to pharmacokinetic studies, as you stated?	10:04:57
8	A. Well, he was involved in, you know,	10:05:03
9	organizing them and getting them run.	10:05:08
10	Q. And this related to cladribine, correct?	10:05:11
11	A. Yes. Yes.	10:05:14
12	Q. Okay. Were you aware of what Dr. Marcus was	10:05:15
13	involved with besides oral cladribine?	10:05:25
14	MS. PHENG: Objection to form.	10:05:28
15	THE WITNESS: I was not aware, no.	10:05:29
16	BY MR. LIU:	10:05:36
17	Q. Was Dr. Marcus at IVAX before you started --	10:05:36
18	A. I don't know.	10:05:40
19	Q. -- at --	10:05:41
20	A. I do not know.	10:05:43
21	Q. Was Dr. Marcus still employed at IVAX after	10:05:46
22	you left?	10:05:49

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1	A. Again, I do not know. I don't recall.	10:05:51
2	Q. And you were at IVAX from 2001 to 2004,	10:06:04
3	correct?	10:06:08
4	A. Yeah, that's correct.	10:06:08
5	Q. Okay. Now, Dr. Dandiker, you are being	10:06:10
6	compensated at your usual consulting rate of	10:06:19
7	\$800 an hour, correct?	10:06:21
8	A. Yes.	10:06:23
9	Q. Dr. Dandiker, how much have you billed so far	10:06:24
10	in this case?	10:06:27
11	A. I'd have to look it up, but something like	10:06:28
12	\$2,000.	10:06:42
13	Q. So you are owed additional money for this	10:06:42
14	case, correct?	10:06:45
15	A. Yes, but I have not, kind of, billed them.	10:06:46
16	Q. Okay. Do you know how many hours you have	10:06:55
17	billed to date for this case?	10:07:04
18	A. I don't really know.	10:07:09
19	Q. Do you -- let me rephrase my question.	10:07:13
20	Do you have an idea of how many hours	10:07:17
21	you've spent to date?	10:07:19
22	A. Yes. Yeah, I have a rough idea.	10:07:21

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1	Q. Okay. And can you approximate that for me?	10:07:24
2	A. Yeah. So as I mentioned earlier, preparation	10:07:31
3	for the declaration was, you know, maybe two	10:07:36
4	days, and then deposition two days.	10:07:38
5	Q. So how many hours total do you think you have	10:07:44
6	spent so far in preparation for your	10:07:47
7	declaration and your deposition?	10:07:50
8	A. Yeah, so I would say, you know, maybe	10:07:52
9	between, you know, 30 to 40 hours.	10:07:56
10	Q. Dr. Dandiker, have you ever received any	10:08:03
11	other compensation from Merck or any related	10:08:07
12	entity outside of preparing your declaration?	10:08:11
13	MS. PHENG: Objection to form.	10:08:14
14	THE WITNESS: Sorry, can you	10:08:17
15	rephrase that question?	10:08:17
16	BY MR. LIU:	10:08:21
17	Q. So what did you not understand for my	10:08:22
18	question?	10:08:23
19	A. I do get compensation from entities other	10:08:24
20	than Merck.	10:08:26
21	Q. Okay. My question was: Have you ever	10:08:34
22	received any compensation outside of your	10:08:38

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1	work on this case from Merck or any related	10:08:41
2	entity to Merck?	10:08:44
3	A. Not on this case.	10:08:46
4	MS. PHENG: Same objection.	10:08:48
5	BY MR. LIU:	10:09:09
6	Q. Okay. My question was: Have you ever	10:09:10
7	received any compensation outside of your	10:09:11
8	work on this case from Merck or any related	10:09:15
9	entity to Merck?	10:09:18
10	A. Not on this case.	10:09:20
11	MS. PHENG: Same objection.	10:09:22
12	BY MR. LIU:	10:09:28
13	Q. The question is not about this case. So have	10:09:29
14	you received any compensation from Merck or	10:09:32
15	any related entities --	10:09:34
16	A. No.	10:09:36
17	Q. -- outside of this case?	10:09:36
18	A. No.	10:09:38
19	MS. PHENG: Same objection.	10:09:39
20	BY MR. LIU:	10:09:53
21	Q. Okay. So you agree with me that putting	10:09:53
22	aside your compensation from Merck on this	10:09:55

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1	case, have you received any compensation from	10:10:00
2	Merck or any of the -- any of -- any related	10:10:04
3	entities to Merck?	10:10:06
4	MS. PHENG: Same objection.	10:10:07
5	THE WITNESS: Yeah, I just want to	10:10:09
6	clarify. So I bill WilmerHale. Presumably,	10:10:10
7	they bill Merck. So I do not directly deal	10:10:17
8	with Merck. And you're -- since you're	10:10:22
9	asking the question several times, I have not	10:10:28
10	received compensation from anybody else.	10:10:30
11	BY MR. LIU:	10:10:35
12	Q. So you have not received compensation from	10:10:35
13	Merck outside of your compensation on this	10:10:38
14	case, correct?	10:10:42
15	A. Yes.	10:10:42
16	Q. And you have not received any compensation	10:10:45
17	from any related entities to Merck outside	10:10:47
18	your compensation for this case, correct?	10:10:52
19	A. Yes, yes.	10:10:54
20	Q. Okay. Dr. Dandiker, you are the CEO of	10:10:57
21	Celista Pharmaceuticals, correct?	10:11:03
22	A. Yes.	10:11:05

1	Q. Has Celista Pharmaceuticals ever received any	10:11:06
2	compensation from Merck or any related	10:11:11
3	entities?	10:11:13
4	A. No.	10:11:13
5	Q. Now, if we could go to your declaration,	10:11:14
6	which I believe it's in front of you.	10:11:23
7	A. Right.	10:11:27
8	Q. If you can go to paragraph 6 of your	10:11:27
9	declaration, you provided your CV as part of	10:11:34
10	your declaration, correct?	10:11:36
11	A. Yes.	10:11:38
12	MS. PHENG: Excuse me, Tyler, will	10:11:41
13	we be pulling it up electronically for	10:11:46
14	everyone else?	10:11:50
15	MR. LIU: Sure.	10:11:51
16	Rachel, you can bring it up as well.	10:11:52
17	THE TECHNICIAN: (Complies.)	10:11:52
18	MR. LIU: So if you go to	10:11:55
19	paragraph 6, which is page 2 of his	10:11:56
20	declaration, so the next page.	10:12:01
21	THE TECHNICIAN: (Complies.)	10:12:06
22	MR. LIU: Yes.	10:12:06

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1	BY MR. LIU:	10:12:06
2	Q. So if you look at paragraph 6, you provide	10:12:06
3	your CV as part of your declaration, correct?	10:12:09
4	A. Yes.	10:12:11
5	Q. Okay. And if we go to Appendix A, which is	10:12:12
6	PDF page 14, starting on paragraph --	10:12:18
7	starting on page 14, the next page, and then	10:12:23
8	the next, so this is the start of your CV,	10:12:28
9	correct?	10:12:32
10	A. Yes.	10:12:32
11	Q. And you provided five -- your CV totals five	10:12:32
12	pages, correct?	10:12:37
13	A. Yes.	10:12:38
14	Q. Dr. Dandiker, when did you last update the	10:12:42
15	CV?	10:12:45
16	A. Oh, that's a good question. Maybe two, three	10:12:47
17	years ago.	10:12:53
18	Q. And you haven't updated it since two, three	10:12:54
19	years ago?	10:12:58
20	A. No. I've had no reason to.	10:12:58
21	Q. Okay. And you would agree that your CV	10:12:59
22	accurately describes your credentials,	10:13:04

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1	correct?	10:13:06
2	A. Yes.	10:13:06
3	Q. Does your CV accurately reflect your areas of	10:13:06
4	scientific expertise?	10:13:11
5	A. Yes.	10:13:13
6	MR. LIU: Okay. You can take that	10:13:18
7	down.	10:13:19
8	THE TECHNICIAN: (Complies.)	10:13:19
9	BY MR. LIU:	10:13:19
10	Q. Dr. Dandiker, we talked about this earlier,	10:13:24
11	but you joined IVAX in 2001, right?	10:13:28
12	A. Yes.	10:13:30
13	Q. And what was your job title at IVAX?	10:13:30
14	A. It was director of R&D.	10:13:34
15	Q. And did your title change while you were at	10:13:38
16	IVAX?	10:13:41
17	A. No, it did not.	10:13:42
18	Q. And while you were at IVAX from 2001 to 2004,	10:13:43
19	were you physically located in the US?	10:13:49
20	A. I was not. I was located in the UK.	10:13:51
21	Q. Okay. And that was where your office was,	10:13:55
22	correct --	10:13:59

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1	A. Yes.	10:14:00
2	Q. -- in the UK?	10:14:00
3	A. Yes.	10:14:01
4	Q. And did you ever move offices while you were	10:14:01
5	at IVAX?	10:14:05
6	A. No, no.	10:14:06
7	Q. And what did your role as director of R&D at	10:14:07
8	IVAX entail?	10:14:14
9	A. I was looking after R&D. And IVAX,	10:14:16
10	fundamentally, was a generic company, so we	10:14:21
11	were developing a number of generic products.	10:14:28
12	Cladribine was actually an exception in that	10:14:32
13	it was not a generic. And I looked after	10:14:38
14	groups in UK, Thailand, India. So those	10:14:42
15	were, kind of, my responsibilities.	10:14:49
16	Q. And how were you involved in the development	10:14:55
17	of an oral cladribine formulation?	10:14:58
18	A. Really from, I think, two perspectives. One	10:15:03
19	is formulating ideas as to what it could be,	10:15:06
20	and then ensuring that the work got done	10:15:08
21	either by myself or through the team.	10:15:14
22	Q. Okay. And you mentioned, "The team." So who	10:15:23

1	was on that team in terms of developing an	10:15:28
2	oral cladribine formulation?	10:15:30
3	A. I would -- at this moment in time, I wouldn't	10:15:32
4	know. I can't recall. A number of current	10:15:33
5	junior scientists who came and went.	10:15:35
6	Q. And you can't recall any of these individual	10:15:39
7	names?	10:15:42
8	A. No, I don't.	10:15:42
9	Q. Was IVAX already working on an oral	10:15:46
10	cladribine formulation prior to you joining	10:15:49
11	the company?	10:15:51
12	A. I -- sorry, can you repeat that question	10:15:54
13	again?	10:15:58
14	Q. Sure. Was IVAX already working on an oral	10:15:59
15	cladribine formulation prior to you joining	10:16:03
16	the company?	10:16:04
17	A. Not that I know.	10:16:05
18	Q. How many people were on the team --	10:16:10
19	MS. PHENG: Objection to form --	10:16:13
20	MR. LIU: -- for cladribine --	10:16:13
21	I'll rephrase.	10:16:13
22	MS. PHENG: -- relevance.	10:16:15

1	BY MR. LIU:	10:16:15
2	Q. I'll rephrase.	10:16:17
3	How many people at IVAX were working	10:16:18
4	on an oral cladribine formulation?	10:16:20
5	A. I would say probably one.	10:16:24
6	Q. You just stated earlier that there were some	10:16:26
7	junior scientists --	10:16:29
8	A. Yeah, but just to clarify again, the purpose	10:16:30
9	for IVAX was to develop generic products. So	10:16:37
10	the focus of the team would have been on the	10:16:39
11	generic products. Cladribine was an	10:16:42
12	exception.	10:16:45
13	And, you know, we would devote some	10:16:46
14	time, but not a whole lot of time to it. And	10:16:52
15	when I say, "One," you know, it's primarily	10:16:55
16	talking about an FTE.	10:16:59
17	So one person could do one piece of	10:17:01
18	work, for example, with a formulation work,	10:17:04
19	another person would do some analytical work,	10:17:08
20	but that does not mean that there's a whole	10:17:12
21	person.	10:17:15
22	Q. Okay. What did you mean by, "FTE"?	10:17:21

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1	Did you say, "FTE"?	10:17:24
2	A. Yeah. Full-time equivalent.	10:17:27
3	Q. Okay. And what does that mean?	10:17:28
4	A. That means somebody is spending a hundred	10:17:30
5	percent of their time on one thing.	10:17:32
6	Q. Okay. And who was that one individual	10:17:34
7	working on --	10:17:35
8	A. I --	10:17:37
9	Q. -- the oral cladribine formulation?	10:17:38
10	A. I can't recall at the moment. Certainly, I	10:17:40
11	was involved, and I did some of the work	10:17:43
12	myself, but I can't recall who else helped	10:17:45
13	me.	10:17:49
14	Q. And so when you're saying full-time	10:17:50
15	equivalent, you're talking about a single	10:17:52
16	person at IVAX working on an oral cladribine	10:17:54
17	formulation?	10:17:57
18	A. No. Let me just clarify this again.	10:17:58
19	What I said was -- and, again, this	10:18:01
20	is, you know, an estimate of time, because	10:18:06
21	it's recollection from 20 years ago. When I	10:18:10
22	say, "Full-time equivalent," that means that	10:18:14

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1 one person may do part of the job, somebody 10:18:17
2 else may do some other part of the job, and 10:18:20
3 then when you make a, you know, cumulative 10:18:23
4 addition, you come up with a number. 10:18:27

5 And that, again, is an estimate. 10:18:30
6 Because, again, to clarify, at IVAX we did 10:18:32
7 not get compensated by hour or we did not 10:18:36
8 monitor our hours. We were all salaried 10:18:40
9 individuals. 10:18:44

10 So, you know, for instance, if 10:18:45
11 somebody read something, that did not mean 10:18:48
12 that they were, you know, charging per hour 10:18:51
13 for reading something, right? And somebody 10:18:54
14 else may help somebody, that does not mean 10:18:57
15 that they would charge the company for 10:18:59
16 helping. 10:19:01

17 So it is -- you know, it's kind of a 10:19:03
18 team of people who were working on many 10:19:09
19 different things and who would do, you know, 10:19:11
20 parts of a project as required. 10:19:13

21 Q. Thank you. Thank you for that explanation. 10:19:17

22 So my question is: How many people 10:19:20

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1	made up the full-time equivalent that you	10:19:23
2	were talking about working on this oral	10:19:25
3	cladribine project at IVAX?	10:19:28
4	A. As I said, my guess would be one. And I	10:19:29
5	would again say it's a guess, because we did	10:19:33
6	not, I would say, monitor our time, or we did	10:19:37
7	not document our time, because we were not	10:19:42
8	required to.	10:19:46
9	Q. And I just want to confirm that you can't	10:19:48
10	remember anybody else's names that worked on	10:20:01
11	the oral cladribine project outside of	10:20:05
12	yourself, correct?	10:20:07
13	A. Yeah. Yeah, that's correct.	10:20:07
14	Q. Okay. And we talked about this earlier, but	10:20:13
15	you left IVAX in February of 2004, correct?	10:20:18
16	A. Yes.	10:20:20
17	Q. Okay. And did you still have access to any	10:20:27
18	documents or communications from IVAX at any	10:20:30
19	point after you left IVAX?	10:20:32
20	A. No, none at all.	10:20:33
21	Q. So you didn't have access to any emails of	10:20:38
22	any sort while -- after you left IVAX,	10:20:40

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1	correct?	10:20:44
2	A. Yes, that's correct.	10:20:44
3	Q. Great.	10:20:47
4	And IVAX entered into a joint	10:20:48
5	research agreement with Serono after you	10:20:52
6	joined IVAX, correct?	10:20:59
7	A. I am not exactly sure about the dates, but I	10:21:03
8	was aware of the agreement. Not -- I haven't	10:21:10
9	seen the agreement, but I was aware that one	10:21:17
10	had been made.	10:21:19
11	Q. Okay. Was there any work done between IVAX	10:21:25
12	and Serono that wasn't under the joint	10:21:30
13	research agreement?	10:21:31
14	MS. PHENG: Objection to form,	10:21:33
15	foundation.	10:21:34
16	THE WITNESS: I -- as far as I	10:21:37
17	know, no. But then I don't know what	10:21:40
18	happened in the US. I was based in the UK.	10:21:46
19	BY MR. LIU:	10:21:53
20	Q. So as far as you know, you were not aware of	10:21:53
21	any work done between IVAX and Serono that	10:21:55
22	wasn't covered under the joint research	10:21:58

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1	agreement, correct?	10:22:01
2	A. Yes, yes.	10:22:01
3	MS. PHENG: Objection to form,	10:22:02
4	foundation.	10:22:03
5	BY MR. LIU:	10:22:04
6	Q. Was there any work done between IVAX and	10:22:10
7	Serono -- are you -- strike that.	10:22:13
8	Are you aware of any work done	10:22:19
9	between IVAX and Serono outside of the UK	10:22:22
10	that wasn't covered under the joint research	10:22:27
11	agreement?	10:22:29
12	MS. PHENG: Objection to form,	10:22:31
13	foundation.	10:22:32
14	THE WITNESS: What I -- I think	10:22:35
15	I -- as mentioned earlier, the formulation	10:22:38
16	work was being done in the UK, but other	10:22:41
17	aspects of the project were being done in the	10:22:45
18	US.	10:22:48
19	BY MR. LIU:	10:22:53
20	Q. Are you aware of any work done between IVAX	10:22:53
21	and Serono outside of the UK?	10:22:56
22	A. Yes, I knew work was being done in the US.	10:23:03

1	Q. And what work was done being in the US?	10:23:08
2	A. For instance, the coordination of the	10:23:11
3	pharmacokinetic studies.	10:23:15
4	Q. Were you aware of any work done between IVAX	10:23:18
5	and Serono outside the US and the UK?	10:23:22
6	A. No, I was not.	10:23:25
7	Q. Were you aware of any other work besides the	10:23:34
8	pharmacokinetics -- strike that.	10:23:38
9	Besides the coordination of the	10:23:48
10	pharmacokinetic studies that were being	10:23:51
11	performed in the US, were you aware of any	10:23:52
12	other work between IVAX and Serono?	10:23:54
13	A. I was not.	10:23:56
14	Q. Do you know who was doing the work on the	10:24:01
15	pharmacokinetic studies in the US?	10:24:03
16	A. I knew Dr. Stephen Marcus was involved.	10:24:09
17	Q. Do you know if anyone else was involved in	10:24:15
18	the pharmacokinetic studies outside of	10:24:17
19	Dr. Marcus?	10:24:19
20	A. I don't. I do not know who Dr. Marcus	10:24:20
21	interacted with.	10:24:29
22	Q. So is it fair to characterize the cladribine	10:24:41

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1	work done between Serono and IVAX as a joint	10:24:46
2	research or collaboration?	10:24:49
3	MS. PHENG: Objection to form.	10:24:52
4	THE WITNESS: Yes.	10:24:53
5	BY MR. LIU:	10:24:59
6	Q. Dr. Dandiker, were you involved in the	10:24:59
7	decision to enter into that joint research	10:25:01
8	agreement?	10:25:03
9	A. I was not.	10:25:05
10	Q. Do you know who was -- whose decision it was	10:25:06
11	to enter into that agreement between IVAX and	10:25:11
12	Serono?	10:25:14
13	A. I don't.	10:25:18
14	Q. Do you -- how many people in the US were	10:25:18
15	working on cladribine?	10:25:27
16	A. I can't answer that. I do not know.	10:25:28
17	Q. So you don't know of anyone else besides	10:25:31
18	Dr. Marcus working on the cladribine project	10:25:34
19	in the US, correct?	10:25:36
20	MS. PHENG: Objection to form.	10:25:38
21	THE WITNESS: My interactions were	10:25:39
22	with, you know, one or two people, and	10:25:42

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1	that was it.	10:25:43
2	BY MR. LIU:	10:25:45
3	Q. How did the agreement between Serono and IVAX	10:25:46
4	come about?	10:25:50
5	MS. PHENG: Objection to form.	10:25:52
6	THE WITNESS: I do not know.	10:25:54
7	BY MR. LIU:	10:25:56
8	Q. So you don't know if Serono approached IVAX	10:25:56
9	or vice versa?	10:25:59
10	MS. PHENG: Objection to form,	10:26:03
11	foundation.	10:26:05
12	THE WITNESS: I mean, that is	10:26:05
13	correct, but my supposition was that IVAX	10:26:07
14	must have approached Serono.	10:26:10
15	BY MR. LIU:	10:26:13
16	Q. And why is that your supposition that IVAX	10:26:13
17	approached Serono?	10:26:17
18	A. Because IVAX is -- you know, was a generic	10:26:18
19	company which did not have the capability	10:26:23
20	of doing a product like cladribine.	10:26:26
21	Q. So do you have an understanding as to why	10:26:40
22	IVAX entered into a joint research agreement	10:26:42

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1	with Serono?	10:26:44
2	A. It's just my supposition. Other people may	10:26:47
3	have different -- a different take on it.	10:26:52
4	But mine was that, you know, Serono were a	10:26:56
5	good partner because they were, at the time,	10:27:00
6	you know, a premier company in the multiple	10:27:04
7	sclerosis field. IVAX did not have that	10:27:14
8	capability.	10:27:16
9	Q. And did IVAX already have an oral cladribine	10:27:16
10	formulation prior to reaching out to Serono?	10:27:19
11	MS. PHENG: Objection to form.	10:27:25
12	THE WITNESS: It all comes back to	10:27:26
13	timing. From what I know, no. But I don't	10:27:31
14	know everything.	10:27:33
15	BY MR. LIU:	10:27:36
16	Q. And do you know who would know that	10:27:36
17	information?	10:27:38
18	A. Well, I think what you're asking is probably	10:27:40
19	a -- you know, there are two questions in	10:27:45
20	one, which is when was the -- you know, when	10:27:47
21	was the collaboration signed, but prior to	10:27:52
22	that, you know, when were the discussions had	10:27:55

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1	and when was the formulation work started.	10:27:58
2	And for me to answer that, it's kind of	10:28:01
3	nearly impossible, because I don't know.	10:28:03
4	Q. So you don't have any idea of when	10:28:06
5	formulation work on oral cladribine began at	10:28:11
6	IVAX?	10:28:15
7	A. I knew when it began in the UK.	10:28:15
8	Q. Okay. When did it begin in the UK?	10:28:19
9	A. Yeah.	10:28:22
10	Q. And when? Sorry. Sorry. When did it begin?	10:28:22
11	A. So it would have been in 2003. I wouldn't	10:28:25
12	know the exact, kind of, date. Maybe 2002,	10:28:27
13	but I wouldn't know. I mean, unless I had	10:28:33
14	access to my lab books at the time, I	10:28:36
15	couldn't put a date to it now.	10:28:39
16	Q. Do you know when formulation work on	10:28:42
17	cladribine began outside of the UK?	10:28:46
18	A. As far as I know, there was no formulation	10:28:52
19	work done on cladribine outside of the UK.	10:28:54
20	Q. And did you yourself work with Serono?	10:28:58
21	A. Yes.	10:29:02
22	Q. And do you know when that started?	10:29:02

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1	A. I don't know when that started. I can't	10:29:08
2	recall, again, exact date. And --	10:29:11
3	Q. Would you say -- oh, sorry, go ahead.	10:29:13
4	A. And just to kind of clarify, again, when you	10:29:16
5	say actual work, if communication is work,	10:29:19
6	then, certainly, yes, I did speak with	10:29:22
7	Serono.	10:29:25
8	Q. And do you know what approximate time frame	10:29:26
9	that was when you started communicating with	10:29:30
10	Serono?	10:29:32
11	A. Yes, I think once the agreement was signed	10:29:33
12	and we were working on the formulation work,	10:29:38
13	certainly we were, you know, communicating	10:29:45
14	quite often.	10:29:49
15	Q. And you had stated earlier about formulation	10:29:50
16	work on cladribine. What did you mean by,	10:29:53
17	"Formulation"?	10:30:01
18	A. So as you know, cladribine was available as	10:30:01
19	an injectable. What we were trying to do was	10:30:07
20	to make the first oral tablet or oral	10:30:11
21	formulation, which is perhaps the right	10:30:17
22	terminology, for cladribine so that it would	10:30:20

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1	help people, it would help patients.	10:30:27
2	Multiple sclerosis is a devastating disease.	10:30:32
3	And in the absence of that, the only	10:30:38
4	way people get therapy is to -- you know, is	10:30:41
5	by injections. And for that, you have to go	10:30:46
6	to a medical practitioner or go to a	10:30:49
7	facility, et cetera, and the costs are, you	10:30:51
8	know, are significant.	10:30:55
9	With an oral formulation, it takes	10:31:00
10	away all of that and, you know, it gives the	10:31:02
11	patient the ability to dose themselves at the	10:31:09
12	right and the appropriate time. And oral, I	10:31:11
13	think, is just better for the patient.	10:31:16
14	Q. Okay. Thank you.	10:31:20
15	And when we were talking about	10:31:32
16	earlier about when you started work or when	10:31:33
17	you communicated with Serono, can you	10:31:38
18	approximate, like, a month or the year of	10:31:41
19	when that was?	10:31:45
20	MS. PHENG: Objection to form.	10:31:46
21	THE WITNESS: I just wouldn't	10:31:47
22	know. I mean, you know, this is, say,	10:31:48

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1	20 years ago.	10:31:52
2	BY MR. LIU:	10:31:59
3	Q. Was it shortly after the agreement was signed	10:31:59
4	by IVAX and Serono?	10:32:03
5	A. Again, for me it's difficult to answer the	10:32:08
6	question, because I do not know when that	10:32:10
7	agreement was actually signed. I became	10:32:11
8	aware of the agreement being signed after the	10:32:16
9	event, so I just don't know how much time	10:32:20
10	elapsed in between.	10:32:22
11	Q. So you agree -- you would agree that you	10:32:31
12	started communicating with Serono after you	10:32:35
13	became aware of the signing between --	10:32:38
14	signing of the agreement between IVAX and	10:32:41
15	Serono, correct?	10:32:42
16	MS. PHENG: Objection to form,	10:32:43
17	foundation.	10:32:44
18	THE WITNESS: Yeah, I would -- I	10:32:46
19	would put it in another way, which is that I	10:32:48
20	did not unilaterally start communicating with	10:32:52
21	Serono once the agreement was signed.	10:32:55
22	Just again, when companies	10:32:59

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1	collaborate on a project, the objective is	10:33:02
2	the same, which is, you know, to get the	10:33:06
3	product done. And so both sides have to --	10:33:08
4	have to talk, and, you know, one side's	10:33:12
5	activities are dependent on the other side,	10:33:18
6	and vice versa, because you cannot not not	10:33:22
7	communicate in a collaboration.	10:33:26
8	So, you know, to put exact dates to	10:33:28
9	this, it's kind of very difficult.	10:33:32
10	BY MR. LIU:	10:33:37
11	Q. So did you start communicating with Serono or	10:33:38
12	did Serono reach out to you --	10:33:40
13	MS. PHENG: Objection to form.	10:33:41
14	BY MR. LIU:	10:33:43
15	Q. -- to begin conversations on this cladribine	10:33:43
16	collaboration?	10:33:47
17	A. I don't know. I don't know. It could be	10:33:47
18	very simple as, you know, somebody getting in	10:33:54
19	touch with somebody in Miami who then got in	10:33:56
20	touch with me. So, you know, it could not	10:34:01
21	even be -- and then as the relationship	10:34:03
22	develops, you know, one starts communicating	10:34:06

1	more directly.	10:34:09
2	Q. And you had stated earlier that, you know,	10:34:13
3	one side's activities are not dependent on	10:34:17
4	the other side's.	10:34:20
5	What did you mean by that?	10:34:21
6	A. No, I actually meant the opposite. I said --	10:34:22
7	Q. Okay.	10:34:25
8	A. -- one side's activities are actually	10:34:26
9	dependent on the other side's. So for	10:34:30
10	example --	10:34:32
11	Q. Okay. And what did you mean by that? I	10:34:32
12	apologize for --	10:34:33
13	A. Yeah, so you know, for, for example, Serono	10:34:34
14	to know whether we have a viable product,	10:34:38
15	they need to know what we are doing. And for	10:34:42
16	us to get comfort that they are able to do	10:34:45
17	the clinical studies, we also need some input	10:34:49
18	from them in terms of, you know, what would	10:34:53
19	be their requirements, what would be patient	10:34:55
20	requirements. As I mentioned earlier that	10:34:58
21	they had far more experience in multiple	10:35:04
22	sclerosis than we did.	10:35:09

1 Q. And you had stated earlier that you did not
2 unilaterally start communicating with IVAX --
3 with Serono once the agreement was signed.

10:35:09

10:35:14

10:35:18

4 Was there anyone at IVAX that told
5 you to start communicating with Serono?

10:35:20

10:35:22

6 A. I think it's -- again, I think perhaps the
7 question needs to be rephrased. It's not
8 that you are told. It's, you know, natural
9 in terms of development where, you know,
10 scientists on both sides talk to each other,
11 because the objective is to, you know, get a
12 product done. So it is not that, okay, on
13 day one you speak and then on day two you
14 don't speak to somebody. It doesn't work
15 that way.

10:35:26

10:35:32

10:35:34

10:35:40

10:35:43

10:35:46

10:35:49

10:35:53

10:35:55

10:35:57

16 Q. Now, you had stated earlier that, for Serono,
17 it was important for them to know whether
18 we -- whether IVAX had a viable product.

10:36:09

10:36:12

10:36:15

19 Why was it important for Serono to
20 know what IVAX was doing?

10:36:19

10:36:21

21 MS. PHENG: Objection to form and
22 foundation.

10:36:22

10:36:26

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1	THE WITNESS: As I mentioned	10:36:27
2	earlier, you know, both sides need to know,	10:36:28
3	in a collaboration, what the other side is	10:36:31
4	doing, right? You cannot develop a product	10:36:34
5	without people knowing. You may be doing	10:36:39
6	completely wrong things. You just -- you	10:36:45
7	need input from everybody. It is a team	10:36:48
8	game.	10:36:51
9	BY MR. LIU:	10:36:51
10	Q. And what kind of information did Serono need	10:36:51
11	to know from IVAX?	10:36:54
12	MS. PHENG: Objection to form,	10:36:55
13	foundation.	10:36:56
14	THE WITNESS: I mean, the basic	10:36:59
15	information, which is, you know, if you're	10:37:01
16	trying to develop an oral formulation of	10:37:05
17	cladribine, are we able to and, you know,	10:37:08
18	what are the options we are looking at, you	10:37:12
19	know, what is likely to be feasible or not	10:37:16
20	feasible or is it going to work at all. I	10:37:21
21	mean, you know, those are things which they	10:37:24
22	need to know.	10:37:26

1	And based on that they can, you know,	10:37:29
2	plan accordingly and invest in the project	10:37:33
3	accordingly.	10:37:35
4	BY MR. LIU:	10:37:43
5	Q. So what specifically did Serono do with the	10:37:43
6	information that you provided -- that IVAX	10:37:46
7	provided regarding the oral formulation of	10:37:49
8	cladribine?	10:37:51
9	MS. PHENG: Objection to form,	10:37:52
10	foundation, relevance.	10:37:54
11	THE WITNESS: I think that's	10:37:54
12	something you have to ask Serono.	10:37:55
13	MS. PHENG: Please let me finish	10:37:57
14	objecting.	10:37:58
15	Go ahead.	10:37:59
16	THE WITNESS: Sorry.	10:37:59
17	So I think in terms of what Serono	10:38:00
18	did with that information, you ought to	10:38:02
19	really ask them.	10:38:07
20	BY MR. LIU:	10:38:09
21	Q. And you had stated earlier that Serono needed	10:38:09
22	to know whether IVAX had a viable product.	10:38:12

1	What did you mean by, "A viable product"?	10:38:16
2	A. Whether IVAX could make an oral formulation	10:38:20
3	of cladribine.	10:38:25
4	Q. Did Serono need to know what IVAX's	10:38:30
5	formulation for oral cladribine was?	10:38:34
6	A. Yes.	10:38:37
7	MS. PHENG: Objection to form,	10:38:38
8	foundation.	10:38:39
9	BY MR. LIU:	10:38:41
10	Q. Okay. Why?	10:38:41
11	A. I think you --	10:38:47
12	MS. PHENG: Same objection.	10:38:48
13	THE WITNESS: I think you cannot	10:38:49
14	develop a product without knowing what it is.	10:38:53
15	BY MR. LIU:	10:38:59
16	Q. And why is that?	10:38:59
17	MS. PHENG: Same objection.	10:39:01
18	THE WITNESS: Well, I mean, how	10:39:07
19	would one go and invest in quite expensive	10:39:11
20	studies without knowing whether -- what the	10:39:14
21	product is? I mean, you need to know that,	10:39:17
22	and how it works and, you know, for instance,	10:39:20

1 what its bioavailability is or whether it's 10:39:25
2 going to work in patients or not. I mean, 10:39:27
3 somebody may just give you a dummy pill 10:39:30
4 otherwise. 10:39:35

5 BY MR. LIU: 10:39:37

6 Q. And why -- and what kind of studies were you 10:39:37
7 referring to when you said, "Expensive 10:39:44
8 studies"? 10:39:47

9 A. You know, again, to kind of clarify -- and, 10:39:48
10 you know, this is already in my declaration, 10:39:53
11 but let me just go through it again. 10:39:56

12 So, basically, with a collaboration, 10:39:58
13 there was a division of responsibilities. So 10:40:00
14 we looked after the formulation and we did 10:40:04
15 the early PK, pharmacokinetic studies. 10:40:08
16 Serono were looking after the rest of it, 10:40:14
17 which is, you know, the phase 2, phase 3 10:40:18
18 clinical studies, regulatory, and ultimately 10:40:21
19 marketing and approval -- approval and 10:40:24
20 marketing of the product. 10:40:26

21 So, you know, although there are 10:40:29
22 different functions working on the project, 10:40:33

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1	every function needs to know what the other	10:40:37
2	person is actually doing. And, you know,	10:40:39
3	Serono needs to know what we are up to for	10:40:43
4	them to be doing their job.	10:40:45
5	Q. And you talked earlier about bioavailability.	10:40:49
6	Like, why did Serono need to know what the	10:40:53
7	bioavailability was --	10:40:57
8	MS. PHENG: Objection --	10:40:57
9	BY MR. LIU:	10:40:57
10	Q. -- for your oral formulation?	10:40:59
11	MS. PHENG: Objection to form,	10:41:02
12	foundation, scope.	10:41:05
13	THE WITNESS: It goes back to, you	10:41:06
14	know, do you have a product or don't you. So	10:41:09
15	for instance, if the bioavailability was,	10:41:10
16	let's say, 5 percent, Serono would have	10:41:14
17	probably killed off the project, because what	10:41:17
18	that would mean is that a patient would need	10:41:21
19	to take a lot of tablets to get the effect,	10:41:24
20	or maybe, you know, 5 percent is just not	10:41:29
21	good enough for the patient.	10:41:35
22	So that's hypothetical, but it is --	10:41:36

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1	you know, that is what it means, that there	10:41:39
2	are certain parameters you need to have to	10:41:41
3	have a viable product.	10:41:46
4	BY MR. LIU:	10:41:57
5	Q. And what parameters do you need to have to	10:41:57
6	have a viable product?	10:42:02
7	MS. PHENG: Objection to form,	10:42:03
8	foundation.	10:42:04
9	THE WITNESS: As I mentioned	10:42:04
10	earlier, you need to know whether you have a	10:42:05
11	formulation, you need to know whether the	10:42:07
12	formulation works, you need to know whether	10:42:10
13	the formulation is stable, you need to know	10:42:12
14	whether you can manufacture it and can you do	10:42:14
15	it, you know, within a reasonable cost.	10:42:18
16	So all of, you know, those and many	10:42:23
17	other factors, actually, come in to	10:42:27
18	developing a product. And, ultimately, you	10:42:29
19	know, does it really work clinically.	10:42:38
20	BY MR. LIU:	10:42:44
21	Q. When we were talking about bioavailability,	10:42:45
22	you mentioned 5 percent would have caused	10:42:46

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1	Serono to probably kill off the project.	10:42:50
2	Was there, like, a cutoff for	10:42:52
3	bioavailability that would have been	10:42:55
4	sufficient?	10:42:59
5	A. No, I think you're picking on --	10:43:00
6	MS. PHENG: Objection to form,	10:43:01
7	scope.	10:43:03
8	THE WITNESS: -- you're picking on	10:43:03
9	something which is hypothetical. So I said	10:43:04
10	hypothetically, you know, that's what they	10:43:07
11	probably would have done. There has never	10:43:10
12	been a discussion on this with Serono.	10:43:13
13	BY MR. LIU:	10:43:22
14	Q. So there was no set percentage of	10:43:23
15	bioavailability that IVAX and Serono were --	10:43:27
16	A. No, not that I was aware of.	10:43:30
17	MS. PHENG: Objection to form,	10:43:32
18	scope, foundation.	10:43:33
19	BY MR. LIU:	10:43:55
20	Q. As part of the joint research between IVAX	10:43:56
21	and Serono on cladribine, there was an IVAX	10:43:59
22	team and a Serono team, correct?	10:44:02

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1	A. Yes. I would qualify that by saying a team	10:44:06
2	is many different people.	10:44:13
3	Q. Yes. And the IVAX team included which	10:44:17
4	individuals besides yourself and Dr. Marcus?	10:44:25
5	A. And Dr. Bodor.	10:44:29
6	Q. Did the IVAX team include anyone else?	10:44:32
7	A. Not that I recall.	10:44:36
8	Q. What did Dr. Bodor contribute to the	10:44:45
9	development of an oral cladribine	10:44:47
10	formulation?	10:44:49
11	MS. PHENG: Objection to form,	10:44:49
12	foundation, scope.	10:44:50
13	THE WITNESS: I think Dr. Bodor	10:44:57
14	had worked on cladribine and cyclodextrin	10:45:01
15	before even I did.	10:45:11
16	BY MR. LIU:	10:45:12
17	Q. And --	10:45:12
18	A. And --	10:45:12
19	Q. Sorry. Go ahead.	10:45:12
20	A. And certainly he had, you know, prior	10:45:16
21	knowledge which I did not have.	10:45:17
22	Q. And what did Dr. Bodor contribute to	10:45:32

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1	the development of a complex	10:45:35
2	cladribine-cyclodextrin complex?	10:45:40
3	MS. PHENG: Objection to form,	10:45:43
4	foundation, scope.	10:45:45
5	THE WITNESS: Again, that is a	10:45:46
6	question which is impossible to answer,	10:45:47
7	because ultimately these type of developments	10:45:49
8	are a team game. By that I mean, you know,	10:45:54
9	people would be -- I and him would be	10:45:59
10	discussing things over and over again. Many	10:46:03
11	times you do ten experiments and none of them	10:46:08
12	work. That doesn't mean that's it. You	10:46:11
13	know, you try and find a way around it.	10:46:14
14	So when you then ask the question	10:46:15
15	what did one person contribute, it's --	10:46:18
16	that's kind of almost impossible to answer,	10:46:22
17	because it is -- you know, it is two people	10:46:25
18	or more people thinking about a problem and	10:46:29
19	trying to solve it.	10:46:32
20	BY MR. LIU:	10:46:34
21	Q. So do you have any understanding of	10:46:34
22	Dr. Bodor's contribution to a complex	10:46:37

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1	cladribine-cyclodextrin complex?	10:46:42
2	MS. PHENG: Objection to form.	10:46:46
3	THE WITNESS: I think it's just	10:46:47
4	what I said, which is that the contribution,	10:46:48
5	you know, came from him, came from me, there	10:46:50
6	could have been other people. So it -- I	10:46:53
7	can't say, look, this was only Dr. Bodor and	10:46:57
8	full stop. It is -- that is not the case.	10:47:00
9	MS. PHENG: Tyler, I don't want to	10:47:05
10	interrupt you, I just want to know, we've	10:47:07
11	been going for an hour, it might be good to	10:47:09
12	take a break soon, if you want to -- I don't	10:47:11
13	know if you're in a good place to stop soon.	10:47:14
14	MR. LIU: Yeah, sure. We can take	10:47:17
15	a break now.	10:47:18
16	THE WITNESS: Okay.	10:47:20
17	THE VIDEOGRAPHER: Okay. We are	10:47:20
18	going off the record. The time is 10:47.	10:47:21
19	(Recess.)	10:47:23
20	THE VIDEOGRAPHER: We are back on	10:57:27
21	the record. The time is 10:57.	10:57:28
22	BY MR. LIU:	10:57:33

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1	Q. Welcome back, Dr. Dandiker.	10:57:33
2	A. Okay.	10:57:35
3	Q. We had talked earlier about Dr. Marcus's role	10:57:36
4	on the IVAX team as part of the joint	10:57:44
5	research. Can you -- besides the -- sorry.	10:57:45
6	Strike that.	10:57:52
7	Besides the pharmacokinetic studies	10:57:52
8	that Dr. Marcus performed, are you aware of	10:57:54
9	any other work from Dr. Marcus as part of the	10:57:56
10	joint research between IVAX and Serono?	10:58:00
11	MS. PHENG: Objection to form,	10:58:03
12	foundation, scope.	10:58:04
13	THE WITNESS: I would say,	10:58:12
14	Dr. Marcus is an M.D., and I -- besides the	10:58:12
15	pharmacokinetic studies, I don't know what	10:58:17
16	else he was involved in.	10:58:19
17	BY MR. LIU:	10:58:21
18	Q. Okay. And did you speak to counsel during	10:58:22
19	break, during our break, about the substance	10:58:25
20	of your testimony?	10:58:27
21	A. No.	10:58:27
22	Q. Okay. Great.	10:58:28

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1	And what was your role on the IVAX	10:58:35
2	team with respect to the joint research on	10:58:38
3	cladribine between IVAX and Serono?	10:58:42
4	A. Really, to provide a formulation of	10:58:45
5	cladribine, you know, so that basically was	10:58:48
6	my role.	10:58:55
7	Q. And Serono also had a team that worked on the	10:59:00
8	cladribine project along with IVAX, correct?	10:59:04
9	A. Yes.	10:59:06
10	Q. How many people were on the Serono cladribine	10:59:07
11	team?	10:59:13
12	MS. PHENG: Objection to scope,	10:59:13
13	form, foundation.	10:59:14
14	THE WITNESS: Well, I knew maybe	10:59:17
15	three or four people, but then I don't know	10:59:23
16	who was -- you know, who their teams were.	10:59:26
17	BY MR. LIU:	10:59:29
18	Q. Okay. And for the three or four people that	10:59:30
19	you do remember, what were their names?	10:59:32
20	A. I think one was a gentleman you mentioned,	10:59:35
21	Dr. Munafo. And then I think there were a	10:59:39
22	few other people who I had come across, and I	10:59:42

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1	can't, you know, recall everybody's names,	10:59:48
2	but I think they are in the -- on one of the	10:59:50
3	exhibits I had seen, the names were	10:59:54
4	mentioned.	10:59:57
5	Q. Do you recall anyone else's name besides	10:59:58
6	Dr. Munafo?	11:00:01
7	A. There's, you know, Marie Lopez. And other	11:00:02
8	than that, I really don't remember who else	11:00:08
9	was on there. If I saw the names, I would --	11:00:11
10	I can -- that would, you know, recall my	11:00:15
11	memory.	11:00:18
12	Q. And what did Dr. -- sorry, I just want to	11:00:19
13	clarify.	11:00:26
14	So besides Dr. Munafo and	11:00:26
15	Dr. Lopez-Bresnahan, you're not -- you can't	11:00:28
16	recall any other names of the Serono team	11:00:32
17	that were involved in the joint research,	11:00:34
18	correct?	11:00:37
19	A. Yes, at this moment in time.	11:00:38
20	Q. Okay. We can talk about your -- so -- strike	11:00:45
21	that.	11:00:47
22	So what did Dr. Munafo contribute to	11:00:48

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1	the joint research between IVAX and Serono?	11:00:51
2	MS. PHENG: Objection to form,	11:00:58
3	foundation.	11:00:59
4	THE WITNESS: Well, from what I	11:00:59
5	recall, that their objective was to provide	11:01:02
6	more the clinical regulatory input for the	11:01:09
7	development program, and that is what they	11:01:14
8	contributed.	11:01:16
9	BY MR. LIU:	11:01:18
10	Q. Do you recall -- strike that.	11:01:19
11	What did Dr. Munafo specifically	11:01:21
12	contribute to the joint research between IVAX	11:01:24
13	and Serono?	11:01:27
14	MS. PHENG: Same objection.	11:01:28
15	THE WITNESS: Did I -- you know,	11:01:31
16	if I went and looked at the records, I	11:01:34
17	wouldn't know at this moment in time what it	11:01:37
18	is specifically.	11:01:39
19	BY MR. LIU:	11:01:42
20	Q. What did Dr. Lopez-Bresnahan contribute to	11:01:48
21	the joint research between IVAX and Serono?	11:01:51
22	MS. PHENG: Objection to form,	11:01:56

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1	foundation.	11:01:58
2	THE WITNESS: What I can recall is	11:01:58
3	certainly she was very knowledgeable on the	11:01:59
4	clinical side.	11:02:04
5	BY MR. LIU:	11:02:07
6	Q. Do you have any understanding of Dr. Lopez's	11:02:07
7	specific contribution to the joint research	11:02:10
8	between IVAX and Serono?	11:02:13
9	MS. PHENG: Same objection.	11:02:18
10	THE WITNESS: Well, certainly I	11:02:19
11	remember her, you know, knowing a lot in	11:02:20
12	terms of how clinical studies should be done	11:02:22
13	for this type of product.	11:02:29
14	BY MR. LIU:	11:02:32
15	Q. And you said that you remember her knowing a	11:02:38
16	lot in terms of how clinical studies should	11:02:40
17	be done. What exactly do you remember?	11:02:42
18	A. Well, I think it's -- my, kind of, statement	11:02:47
19	is a general statement, and I wouldn't, at	11:02:50
20	this moment in time, know the particulars.	11:02:53
21	Q. So you can't be more specific as to what	11:02:57
22	exactly Dr. Lopez contributed to the joint	11:02:59

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1	research between IVAX and Serono?	11:03:04
2	MS. PHENG: Objection to form,	11:03:07
3	foundation.	11:03:08
4	THE WITNESS: Yes, I would -- I	11:03:08
5	would say that unless one went to the	11:03:09
6	records, I wouldn't know at this moment in	11:03:13
7	time at what -- you know, what each	11:03:15
8	individual contributed 20 years ago.	11:03:20
9	BY MR. LIU:	11:03:26
10	Q. Okay. And you can't be more specific as to	11:03:26
11	what exactly Dr. Munafo contributed to the	11:03:30
12	joint research between IVAX and Serono?	11:03:33
13	A. Well, again, Dr. Munafo I know was -- from	11:03:36
14	what I recall, was actually, you know, a very	11:03:40
15	good clinical contributor. Other than that,	11:03:45
16	I can't remember other things.	11:03:49
17	But, certainly, I did speak with him	11:03:54
18	about what their needs might be when it came	11:03:58
19	to formulation.	11:04:03
20	Q. And when you say, "Clinical contributor,"	11:04:03
21	what do you mean exactly?	11:04:06
22	A. When you do a clinical study, there are many,	11:04:07

1	many aspects one looks at. First and	11:04:10
2	foremost is what should be a design of a	11:04:15
3	study. Secondly, can it even be done.	11:04:19
4	And in this particular case, doing a	11:04:21
5	clinical study is difficult, because you have	11:04:24
6	to do a study in actual patients. And these	11:04:29
7	are patients which are, you know, not in the	11:04:32
8	best of health.	11:04:36
9	And getting patients on a new therapy	11:04:37
10	for long periods of time is difficult. It's	11:04:41
11	difficult for the patient. And what if	11:04:45
12	something does not work? You know, you run	11:04:47
13	the risk of having quite dire consequences	11:04:50
14	for the patient. So it -- you know, there	11:04:55
15	are many aspects which go into deciding this.	11:04:58
16	And then beyond that, you know, so	11:05:03
17	the patient is, let's say, a primary	11:05:07
18	customer, but the other primary customer are	11:05:10
19	the regulators. So when you do a clinical	11:05:12
20	study, the regulators are looking at what are	11:05:15
21	the measures, you know, what is -- what would	11:05:20
22	make a good therapy.	11:05:23

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1	And there are some -- let's say some	11:05:25
2	diseases where, you know, it's -- that's not	11:05:30
3	easy to determine, multiple sclerosis being	11:05:34
4	one, where, you know, there's slow	11:05:41
5	progression of somebody getting worse. So	11:05:44
6	when do you say something is actually	11:05:47
7	working. And so those things are difficult.	11:05:49
8	And then beyond that, it is -- you	11:05:52
9	know, when you've treated somebody, what if	11:05:56
10	they get the disease again. You know, have	11:05:59
11	you really treated them, or are they going to	11:06:01
12	relapse. You know, is that treatment?	11:06:05
13	So there are many factors which go	11:06:06
14	into -- you know, when you say developing a	11:06:08
15	product clinically, there are many aspects	11:06:11
16	and factors which go into play.	11:06:15
17	Q. So what aspects of the clinical study did	11:06:18
18	Dr. Munafo specifically contribute to as part	11:06:22
19	of the joint research?	11:06:25
20	MS. PHENG: Objection to form,	11:06:27
21	foundation, scope --	11:06:28
22	THE WITNESS: I can't really	11:06:29

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1	answer that --	11:06:33
2	MS. PHENG: Sorry, Dr. Dandiker,	11:06:34
3	please just make sure I finish objecting so	11:06:35
4	we don't speak over each other --	11:06:38
5	THE WITNESS: Sure.	11:06:38
6	MS. PHENG: -- for the court	11:06:40
7	reporter.	11:06:40
8	BY MR. LIU:	11:06:40
9	Q. Sorry. Go ahead.	11:06:41
10	A. Yeah. I can't recall specifically. As I	11:06:42
11	mentioned, you know, there are many, many,	11:06:45
12	many aspects which go into this. So, you	11:06:47
13	know, you can't say somebody said, you know,	11:06:49
14	just A. They may have contributed to B, C, D	11:06:53
15	and E as well. So, you know, it's difficult	11:06:59
16	to pin that down.	11:07:02
17	Q. So do you know what aspects of the clinical	11:07:06
18	study did Dr. Lopez specifically contribute	11:07:08
19	to as part of the joint research?	11:07:12
20	MS. PHENG: Objection to form,	11:07:15
21	foundation, scope.	11:07:16
22	THE WITNESS: As I mentioned	11:07:23

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1	earlier, Serono's responsibilities were to	11:07:24
2	conduct the clinical studies. And the	11:07:26
3	assumption there is that those clinical	11:07:33
4	studies will be designed, conducted and	11:07:42
5	executed by people of Serono, which includes	11:07:44
6	Dr. Munafo, Dr. Lopez, and, you know, there	11:07:46
7	may be many other people and teams behind	11:07:49
8	them who I don't know of.	11:07:51
9	BY MR. LIU:	11:07:54
10	Q. So you don't recall specifically what aspects	11:07:55
11	of the clinical study that Dr. Lopez	11:07:58
12	contributed to from Serono, correct?	11:08:01
13	MS. PHENG: Objection to form,	11:08:04
14	foundation, scope.	11:08:05
15	THE WITNESS: Yeah, I recall	11:08:07
16	sitting through presentations by Dr. Lopez,	11:08:10
17	but today I cannot say, Look, this is what	11:08:12
18	Dr. Lopez said.	11:08:17
19	BY MR. LIU:	11:08:19
20	Q. Do you recall with any specificity as to what	11:08:20
21	the presentations by Dr. Lopez were about?	11:08:22
22	MS. PHENG: Objection to form,	11:08:26

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1	scope.	11:08:27
2	THE WITNESS: No. Unless I had	11:08:30
3	the slide in front of me today, I would not	11:08:32
4	be able to. I don't want to misspeak either	11:08:34
5	in terms of what was said.	11:08:38
6	BY MR. LIU:	11:08:39
7	Q. But you do recall sitting -- or sitting and	11:08:39
8	listening to presentations from Dr. Lopez,	11:08:42
9	correct?	11:08:43
10	A. Yeah, yeah.	11:08:44
11	Q. Do you recall how many presentations you	11:08:45
12	remember from Dr. Lopez?	11:08:49
13	A. Certainly one, but I don't know whether there	11:08:51
14	were others. But certainly one I do	11:08:55
15	remember.	11:08:57
16	Q. Do you recall Dr. Munafo presenting on	11:08:58
17	anything relating to clinical studies or	11:09:01
18	anything --	11:09:04
19	MS. PHENG: Objection to form.	11:09:05
20	BY MR. LIU:	11:09:06
21	Q. Strike that.	11:09:06
22	Do you recall any presentations by	11:09:06

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1	Dr. Munafo?	11:09:08
2	A. I don't.	11:09:09
3	Q. So you do recall at least one presentation	11:09:15
4	from Dr. Lopez, correct?	11:09:19
5	A. Yes, yes.	11:09:20
6	Q. What was that presentation about?	11:09:21
7	A. It was about clinical studies.	11:09:26
8	Q. What aspects of clinical studies did she	11:09:28
9	present on?	11:09:34
10	A. Again, you know, it's difficult for me to	11:09:34
11	recall at this moment in time. But, you	11:09:38
12	know, I think it was about how we would go	11:09:41
13	about doing, you know, phase 2, phase 3	11:09:43
14	studies for this indication.	11:09:46
15	Q. Do you recall when this presentation was?	11:09:50
16	A. Yeah, I remember the presentation was at a	11:09:53
17	meeting in Amsterdam which I attended.	11:09:59
18	Q. Are you referring to the August 2003	11:10:06
19	meeting --	11:10:08
20	A. Yes.	11:10:08
21	Q. -- in Amsterdam?	11:10:08
22	A. Yes.	11:10:08

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1	Q. Do you recall who was at that meeting?	11:10:09
2	A. Yeah, I think there were kind of, you know, a	11:10:11
3	bunch of people from Serono, and then from	11:10:15
4	the IVAX side it was myself and Dr. Marcus.	11:10:18
5	Q. Do you recall who from Serono attended	11:10:25
6	besides Dr. Lopez?	11:10:27
7	A. Yeah, there was I think Dr. Lopez,	11:10:29
8	Dr. Munafo, and there were other people who I	11:10:31
9	can't recall at this moment in time.	11:10:35
10	Q. And from IVAX it was just you and Dr. Marcus,	11:10:42
11	is that what you said?	11:10:48
12	A. From what I remember.	11:10:49
13	Q. Okay. And back to the presentation from	11:10:49
14	Dr. Lopez, what was suggested from Dr. Lopez	11:10:51
15	about how to go about performing these	11:10:55
16	clinical studies?	11:10:59
17	A. I wouldn't know --	11:11:00
18	MS. PHENG: Objection to form --	11:11:00
19	THE WITNESS: -- at this moment in	11:11:00
20	time.	11:11:02
21	MS. PHENG: -- foundation, scope.	11:11:02
22	BY MR. LIU:	11:11:04

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1	Q. Do you recall with any specificity beyond the	11:11:08
2	clinical studies from this presentation?	11:11:11
3	A. I would just like to kind of clarify that,	11:11:13
4	you know, that is not my -- it's not my	11:11:15
5	expertise, so I really -- I would leave that	11:11:20
6	to the experts and to the experts to clarify	11:11:22
7	what they said. It -- you know, again, I	11:11:27
8	can't speak for somebody and in an area where	11:11:31
9	I have no expertise.	11:11:36
10	Q. Did Dr. Munafo present at the August 2003	11:11:37
11	meeting?	11:11:40
12	A. I believe so. I'm not --	11:11:41
13	Q. But -- oh, sorry. Go ahead.	11:11:45
14	A. Yeah, I'm not sure, but I would have to look	11:11:48
15	at the minutes, really. But, I mean, I	11:11:50
16	believe he was there.	11:11:54
17	Q. Who else presented from Serono at the	11:11:59
18	August 2003 meeting?	11:12:02
19	A. The only person I remember is Dr. Lopez.	11:12:04
20	And, obviously, there were other people who	11:12:08
21	were contributing. But in terms of a	11:12:10
22	presentation, the only presentation I recall	11:12:17

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1	is from Dr. Lopez.	11:12:18
2	Q. Did you communicate with Dr. Munafo outside	11:12:21
3	of him presenting?	11:12:24
4	MS. PHENG: Objection to form.	11:12:28
5	THE WITNESS: I think as I	11:12:32
6	mentioned earlier that, you know, there were	11:12:33
7	regular communications between the two	11:12:36
8	companies.	11:12:38
9	BY MR. LIU:	11:12:42
10	Q. Did you have communications with Dr. Munafo	11:12:43
11	at the August 2003 meeting?	11:12:46
12	A. I'd have to look at the minutes of the	11:12:51
13	meeting, but I -- I would -- you know, I	11:12:53
14	would say that I would -- you know, I would	11:12:58
15	be speaking to Dr. Munafo if he was -- you	11:13:00
16	know, whether he was there or not anyway.	11:13:04
17	Q. Do you recall any discussions with Dr. Munafo	11:13:08
18	at the August 2003 meeting?	11:13:10
19	A. I don't.	11:13:12
20	Q. Do you recall having discussions with	11:13:13
21	Dr. Lopez at the August 2003 meeting?	11:13:19
22	A. I -- the only thing I recall is sitting	11:13:22

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1	through her presentation.	11:13:26
2	Q. So outside of sitting at her presentation,	11:13:29
3	you did not have any further communications	11:13:32
4	with Dr. Lopez at the August 2003 meeting?	11:13:34
5	A. We may have discussed aspects of the	11:13:39
6	presentation, but I don't -- I wouldn't know	11:13:43
7	what specifics we would have discussed. I	11:13:45
8	mean, I think with all these meetings, with	11:13:50
9	all these presentations, after somebody	11:13:55
10	presents, there are always, you know,	11:13:59
11	questions, discussions, et cetera.	11:14:03
12	So, you know, that may have occurred.	11:14:04
13	But, you know, to say, okay, what	11:14:07
14	specifically was discussed, I wouldn't be	11:14:10
15	able to say that.	11:14:11
16	Q. Do you recall Dr. Marcus having any	11:14:16
17	discussions with Dr. Lopez at this 2003	11:14:19
18	meeting?	11:14:27
19	A. Dr. Marcus was at the meeting so, you know,	11:14:27
20	everybody who was on the meeting must have	11:14:30
21	spoken to each other.	11:14:35
22	Q. How long did this August 2003 meeting last?	11:14:36

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1	A. Again, difficult for me to put a number on	11:14:39
2	it, but I thought it was a one-day meeting.	11:14:43
3	But don't quote me on that. I mean, I	11:14:46
4	thought it was a one-day meeting.	11:14:49
5	Q. Were there other meetings between IVAX and	11:14:51
6	Serono outside of the August 2003 meeting in	11:14:54
7	Amsterdam?	11:14:58
8	A. In Amsterdam, I don't know. I only attended	11:14:59
9	for my piece and stayed for that day and, I	11:15:06
10	think, got back.	11:15:09
11	Q. Did IVAX and Serono have any meetings	11:15:13
12	beside -- in-person meetings besides the	11:15:17
13	August 2003 meeting?	11:15:20
14	MS. PHENG: Objection to scope,	11:15:22
15	foundation and form.	11:15:23
16	THE WITNESS: Yes, I would say	11:15:26
17	they must have. You cannot learn a project	11:15:27
18	like this by just having one meeting.	11:15:31
19	BY MR. LIU:	11:15:33
20	Q. And you stated that in Amsterdam you only	11:15:33
21	attended for your piece. So how long were	11:15:36
22	you at the meeting?	11:15:41

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1 A. Sorry. Again, to clarify, when I said I

11:15:42

2 attended for my piece, I meant my purpose for

11:15:46

3 being there was to really communicate what we

11:15:51

4 had done on the formulation side, and also

11:15:56

5 hear from Serono what their plans were.

11:16:03

6 And with all these meetings, you

11:16:06

7 know, it's not that one side presents and the

11:16:09

8 other side listens. It's that jointly we

11:16:12

9 say, okay, maybe we need to do something a

11:16:15

10 little different.

11:16:17

11 And, you know, so the purpose of the

11:16:18

12 meeting is not only to communicate, but also

11:16:20

13 to determine what the way forward might be.

11:16:23

14 Q. So did you provide input on any of the

11:16:33

15 presentations with Dr. Munafo and Dr. Lopez?

11:16:37

16 A. I might have, but I can't really recall at

11:16:42

17 this moment in time. Although it's not my

11:16:45

18 area of expertise, I'm not somebody who would

11:16:47

19 just sit there and stay quiet. So, you know,

11:16:50

20 I may have said something.

11:16:56

21 Q. Do you recall any input being provided from

11:16:58

22 the Serono team on any of the presentations

11:16:59

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1	that IVAX presented?	11:17:02
2	A. Oh, yes, of course.	11:17:03
3	MS. PHENG: Objection to form.	11:17:05
4	THE WITNESS: Yes.	11:17:08
5	BY MR. LIU:	11:17:09
6	Q. Do you recall what the input was?	11:17:11
7	A. Yeah, the input may be on, you know, how	11:17:15
8	feasible this formulation is, is it going to	11:17:19
9	work, can we make it, is it good enough. So	11:17:21
10	those kind of things, you know, we do expect	11:17:24
11	the other side to question us on, and they	11:17:27
12	must have.	11:17:31
13	Q. Did IVAX provide input on what Serono could	11:17:32
14	have done differently?	11:17:38
15	MS. PHENG: Objection to form,	11:17:41
16	foundation, scope.	11:17:43
17	THE WITNESS: Again, I -- for me	11:17:45
18	it's very difficult to say anything on that.	11:17:47
19	Because, you know, as I mentioned earlier,	11:17:51
20	there were clear division of	11:17:54
21	responsibilities.	11:17:57
22	Although there was a lot of	11:17:58

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1	communication between the two, there was	11:17:59
2	clear division of responsibilities, which is	11:18:03
3	we were responsible for the formulation, they	11:18:06
4	were responsible for the clinical.	11:18:08
5	And so we may have said, Look, why	11:18:10
6	don't you do it this way or that way, and	11:18:12
7	they may say, This is the reason why we don't	11:18:14
8	do it this way, and that's a learning for us.	11:18:17
9	But you know -- and that's, you know,	11:18:20
10	ongoing, kind of, human, kind of,	11:18:23
11	communication, right?	11:18:25
12	So, you know, it's not that when they	11:18:25
13	presented we sat there, did not say a word,	11:18:29
14	and when we presented, they sat there and	11:18:32
15	didn't say a word. That's not how it works.	11:18:35
16	BY MR. LIU:	11:18:40
17	Q. Dr. Dandiker, are you aware of an individual	11:18:41
18	named Arnaud Ythier? And I'll spell it for	11:18:43
19	you. First name A-R-N-A-U-D, last name	11:18:48
20	Y-T-H-I-E-R.	11:18:53
21	A. I recall the name, but I can't -- I don't	11:18:56
22	remember the person at this moment in time.	11:19:03

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1	I mean, I do recall the name.	11:19:05
2	Q. Did you ever communicate with Dr. Ythier?	11:19:09
3	A. I don't think so, no.	11:19:14
4	Q. Okay. Dr. Dandiker, are you aware of an	11:19:18
5	individual named -- I'm just going to -- I'm	11:19:27
6	just going to spell it for you, first name	11:19:30
7	G-I-A-N-P-I-E-R-O, last name D-E-L-U-C-A?	11:19:31
8	A. Again, I recall the name. I would be -- I	11:19:44
9	wouldn't, at this moment in time, know what	11:19:51
10	they actually did.	11:19:53
11	Q. Did you ever communicate -- oh, sorry. Go	11:19:54
12	ahead. I didn't mean --	11:19:56
13	A. Sometimes you recall a name because, you	11:19:58
14	know, they are on something which -- on a set	11:20:00
15	of minutes or something you have seen. But	11:20:05
16	I -- at this moment in time, I just don't	11:20:07
17	know. And I did not communicate directly,	11:20:10
18	no.	11:20:14
19	Q. So you did not communicate with Dr. deLuca --	11:20:14
20	A. Yeah.	11:20:14
21	Q. -- at all?	11:20:20
22	Okay. Great. Are you aware --	11:20:21

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1	strike that.	11:20:35
2	Do you have an understanding of	11:20:37
3	whether Dr. Ythier contributed to developing	11:20:40
4	the dosing regimen for treating multiple	11:20:43
5	sclerosis with oral cladribine?	11:20:47
6	A. No, I --	11:20:50
7	MS. PHENG: Objection to form.	11:20:50
8	THE WITNESS: I cannot comment on	11:20:52
9	that.	11:20:53
10	BY MR. LIU:	11:20:57
11	Q. Do you have an understanding of whether	11:20:57
12	Dr. deLuca contributed to developing the	11:20:59
13	dosing regimen for treating multiple	11:21:02
14	sclerosis with oral cladribine?	11:21:04
15	A. No, I --	11:21:06
16	MS. PHENG: Objection to form,	11:21:07
17	scope.	11:21:08
18	THE WITNESS: I cannot -- I cannot	11:21:09
19	say anything on that.	11:21:12
20	BY MR. LIU:	11:21:17
21	Q. So who did you communicate with from the	11:21:17
22	Serono team?	11:21:20

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1	A. I think, from what I recall, it was mostly	11:21:23
2	Dr. Munafo. And then Dr. Lopez I got to know	11:21:25
3	over time. And those are the two individuals	11:21:29
4	I remember.	11:21:32
5	Q. Okay. Do you recall communicating with	11:21:35
6	Dr. Lopez?	11:21:38
7	A. Yeah, I would say not only on a professional	11:21:40
8	sense, but also, you know, we'd kind of touch	11:21:45
9	base in terms of how things were going.	11:21:50
10	Q. Did you communicate with Dr. Lopez after you	11:21:54
11	left IVAX?	11:21:57
12	A. No.	11:21:57
13	Q. Did you email directly with Dr. Lopez?	11:21:58
14	A. I don't remember. No, I don't know.	11:22:11
15	Q. So you only recall -- oh, sorry. Go ahead.	11:22:15
16	A. Sorry. I would just say that I would not	11:22:19
17	email somebody without other people being	11:22:23
18	copied on that email. So when you say	11:22:26
19	direct, there would be -- if it was	11:22:32
20	important, there would be many other people	11:22:34
21	on it.	11:22:36
22	Q. Did you ever directly email Dr. Lopez without	11:22:36

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1	people being copied?	11:22:42
2	A. No.	11:22:43
3	Q. Do you recall ever emailing Dr. Lopez at all?	11:22:44
4	A. I don't, actually.	11:22:50
5	Q. But you do recall emailing Dr. Munafo,	11:22:52
6	correct?	11:22:55
7	A. I would say I do recall communicating with	11:22:57
8	Dr. Munafo. Now, you know, we must have	11:23:00
9	spoken over the phone, we could have emailed	11:23:05
10	each other, and I wouldn't know the	11:23:08
11	specifics.	11:23:09
12	Q. On emails between you and Dr. Munafo, who	11:23:15
13	else was copied on those emails?	11:23:20
14	A. I don't know the specifics.	11:23:22
15	Q. So the work that you and your team at IVAX	11:23:29
16	performed resulted in a solid oral dosage	11:23:36
17	form of cladribine that you have referred to	11:23:38
18	throughout your declaration as a complex	11:23:39
19	cladribine-cyclodextrin complex, correct?	11:23:42
20	A. Yes.	11:23:46
21	Q. Now, this complex cladribine-cyclodextrin	11:23:52
22	complex is described in the Bodor PCT	11:23:57

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1	application, correct?	11:24:00
2	A. Yes.	11:24:01
3	Q. And you would agree that this complex	11:24:02
4	cladribine-cyclodextrin complex is your	11:24:06
5	invention, correct?	11:24:08
6	A. Well, it's Dr. Bodor's and mine, and that is	11:24:10
7	why our names are on the patent.	11:24:16
8	MR. LIU: Let's bring up Tab 2,	11:24:29
9	which is the Bodor PCT, Exhibit 1022.	11:24:31
10	THE TECHNICIAN: (Complies.)	11:24:31
11	BY MR. LIU:	11:24:31
12	Q. Can you see that, Dr. Dandiker?	11:24:52
13	A. Yes.	11:24:53
14	Q. Okay. And Dr. Dandiker, this is the Bodor	11:24:54
15	PCT application, correct?	11:24:57
16	A. Yes.	11:24:59
17	Q. Now, if we could go to Item 75 on the left	11:25:00
18	where it states the inventors.	11:25:05
19	Dr. Dandiker, this Bodor PCT lists	11:25:10
20	you and Dr. Bodor as inventors, correct?	11:25:14
21	A. Right.	11:25:17
22	Q. And do you stand by the disclosures of your	11:25:19

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1	Bodor PCT application?	11:25:23
2	A. Yes.	11:25:25
3	MR. LIU: Okay. Rachel, you can	11:25:30
4	take that down.	11:25:34
5	THE TECHNICIAN: (Complies.)	11:25:34
6	BY MR. LIU:	11:25:34
7	Q. Dr. Bodor -- I mean, Dr. Dandiker -- I	11:25:35
8	apologize -- did you read the Bodor PCT	11:25:37
9	before it was filed?	11:25:39
10	A. I may have reviewed it.	11:25:41
11	Q. Did you read the Bodor PCT before you signed	11:25:42
12	your declaration?	11:25:50
13	MS. PHENG: Objection to form.	11:25:51
14	THE WITNESS: I do recall having	11:25:53
15	read the claims.	11:25:56
16	BY MR. LIU:	11:26:03
17	Q. Is that all you recall reading before you	11:26:03
18	signed your declaration?	11:26:06
19	A. Yes.	11:26:07
20	Q. I just want to clarify, before signing your	11:26:12
21	declaration, you only read the claims of the	11:26:17
22	Bodor PCT application, correct?	11:26:19

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1	MS. PHENG: Objection to form.	11:26:21
2	THE WITNESS: Sorry, can you	11:26:25
3	clarify that? Before -- I mean, when you say	11:26:26
4	declaration, what declaration are we	11:26:30
5	referring to?	11:26:33
6	BY MR. LIU:	11:26:33
7	Q. I'm talking about the declaration that you	11:26:35
8	submitted in the proceeding.	11:26:36
9	A. So the declaration --	11:26:44
10	Q. Let me -- sorry.	11:26:45
11	A. Sorry.	11:26:48
12	Q. Let me repeat the question.	11:26:48
13	So after you were retained by Merck,	11:26:49
14	did you read the Bodor PCT?	11:26:52
15	A. Only in terms of the preparation for this	11:26:56
16	deposition.	11:27:01
17	Q. Okay. And what parts of the Bodor PCT did	11:27:03
18	you read after being retained?	11:27:08
19	A. Yeah, I mean, yes, just to kind of -- you	11:27:11
20	know, to clarify what I said earlier, so I	11:27:17
21	did read the claims and I did read some of	11:27:20
22	the specification.	11:27:22

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1	Q. Do you recall what parts of the specification	11:27:25
2	you read?	11:27:26
3	A. Very quickly, I would say I just scan read	11:27:30
4	everything. And then, you know, my focus is	11:27:34
5	always on the claims.	11:27:36
6	Q. And did you read the Bodor PCT after you were	11:27:46
7	retained by Merck and before you signed your	11:27:49
8	declaration in this proceeding?	11:27:51
9	A. No. No. So, sorry, just to -- again, I want	11:27:53
10	to just be clear here. So I read the PCT in	11:27:59
11	preparation, and I also read a little bit of	11:28:06
12	it before the declaration, and the reason	11:28:11
13	being that, you know, that was the main thing	11:28:18
14	the declaration is about, so I had to go back	11:28:21
15	and read it.	11:28:24
16	Q. So before you were retained by Merck, when	11:28:27
17	was the last time you read the Bodor PCT?	11:28:30
18	A. Oh, that was maybe when it was filed, which	11:28:34
19	was many years ago, because there was no	11:28:41
20	reason for me to go back and read it.	11:28:45
21	Q. Dr. Dandiker, did you draft any portion of	11:28:53
22	the Bodor PCT?	11:28:56

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1	MS. PHENG: Objection. I'm going	11:28:58
2	to caution the witness not to reveal the	11:28:59
3	substance of any communication with counsel.	11:29:02
4	You may answer.	11:29:08
5	THE WITNESS: Yeah, I -- it was --	11:29:09
6	from what I recall, you know, it was drafted	11:29:14
7	by counsel and --	11:29:16
8	BY MR. LIU:	11:29:20
9	Q. And -- oh, sorry. Go ahead.	11:29:21
10	A. And my purpose was just to, you know, give	11:29:27
11	them the information and then they drafted	11:29:29
12	it.	11:29:31
13	Q. Do you recall who that was that drafted the	11:29:33
14	PCT --	11:29:35
15	A. I don't at this moment in time, no.	11:29:36
16	Q. So based on your recollection, only counsel	11:29:46
17	was involved in drafting the Bodor PCT?	11:29:49
18	A. As far as --	11:29:52
19	MS. PHENG: Objection to form.	11:29:52
20	THE WITNESS: Sorry. As far as I	11:29:55
21	was concerned, yes. Now, I don't know who	11:29:58
22	else would have drafted anything. But as far	11:30:00

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1	as I knew, it was counsel.	11:30:04
2	BY MR. LIU:	11:30:09
3	Q. Do you recall if this counsel was IVAX	11:30:11
4	in-house counsel or outside counsel?	11:30:13
5	MS. PHENG: Objection to form.	11:30:16
6	THE WITNESS: I believe it was	11:30:19
7	in-house counsel, but I don't know whether	11:30:26
8	the counsel had just come to IVAX to get my	11:30:31
9	input. But at the time, I just assumed that	11:30:37
10	this must have been an IVAX counsel. But it	11:30:40
11	could have been somebody who just came to get	11:30:44
12	the information. I don't know.	11:30:48
13	BY MR. LIU:	11:31:02
14	Q. Dr. Dandiker, were you required to keep the	11:31:04
15	complex cladribine-cyclodextrin complex	11:31:07
16	confidential before the Bodor PCT application	11:31:11
17	was filed in March 2004?	11:31:14
18	MS. PHENG: Objection to form,	11:31:17
19	scope, relevance.	11:31:19
20	THE WITNESS: When you say,	11:31:25
21	"Required," I would say it's just the normal	11:31:26
22	way we work. We keep everything confidential	11:31:29

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1	until -- until, you know, we have a -- some	11:31:32
2	assurance that we are protected.	11:31:36
3	BY MR. LIU:	11:31:39
4	Q. And you did keep it confidential --	11:31:39
5	A. Yes, yes.	11:31:43
6	Q. So IVAX as a company did -- sorry, let me	11:31:44
7	strike that.	11:31:49
8	Did IVAX as a company keep your	11:31:49
9	complex cladribine-cyclodextrin complex	11:31:53
10	confidential from the public before filing	11:31:57
11	the Bodor PCT application?	11:32:01
12	MS. PHENG: Objection to form,	11:32:02
13	foundation, scope, relevance --	11:32:02
14	THE WITNESS: I can only speak for	11:32:05
15	myself.	11:32:05
16	MS. PHENG: Sorry, Dr. Dandiker,	11:32:06
17	please let me finish.	11:32:06
18	THE WITNESS: Sorry.	11:32:06
19	MS. PHENG: I just --	11:32:07
20	THE WITNESS: Sorry.	11:32:07
21	MS. PHENG: -- want to make it	11:32:07
22	clear for the record. Sorry. I'll start	11:32:08

1 over, because I don't think we caught all of 11:32:11

2 it on the realtime. 11:32:13

3 Objection to form, scope, relevance, 11:32:14

4 foundation. 11:32:17

5 THE WITNESS: Yeah, I can only 11:32:19

6 speak to myself. I cannot speak with -- 11:32:21

7 speak about, you know, the rest of IVAX in 11:32:23

8 terms of whether they kept information 11:32:27

9 confidential or not. I cannot. I wouldn't 11:32:29

10 know. 11:32:33

11 BY MR. LIU: 11:32:33

12 Q. So to the best of your knowledge, IVAX, as a 11:32:39

13 company, did keep your complex 11:32:43

14 cladribine-cyclodextrin complex confidential 11:32:48

15 from the public before filing of the Bodor 11:32:50

16 PCT application, correct? 11:32:56

17 MS. PHENG: Objection; scope, 11:32:57

18 relevance, form. 11:32:59

19 THE WITNESS: To the best of my 11:33:02

20 knowledge. 11:33:03

21 BY MR. LIU: 11:33:11

22 Q. Dr. Dandiker, what did you specifically 11:33:12

1	contribute to the complex	11:33:16
2	cladribine-cyclodextrin complex formulation	11:33:18
3	described in the Bodor PCT?	11:33:20
4	A. We -- again, from what I recall, we went and	11:33:23
5	actually tried to make it in the lab. And	11:33:28
6	more specifically, I think there were a	11:33:31
7	number of things which came out of that.	11:33:34
8	Firstly, we were able to identify	11:33:38
9	what kind of ratio we need of the drug to the	11:33:41
10	complex to make an appropriate formulation.	11:33:46
11	If you have too much cyclodextrin, you won't	11:33:54
12	get the drug released. If you have too	11:33:56
13	little, you'll have, you know, a drug which	11:33:59
14	may degrade. So we were able to identify	11:34:02
15	that, which was good.	11:34:05
16	The second thing I also remember is	11:34:06
17	that this complex is also amorphous. And so	11:34:10
18	we developed the process for lyophilization	11:34:15
19	for it. And, again, many people, you know,	11:34:24
20	looking from the outside, may see that as	11:34:27
21	being unusual. Because, you know, if you had	11:34:30
22	to get rid of liquid, why not just filter it	11:34:33

1	or dry it.	11:34:37
2	But the reason to go with	11:34:38
3	lyophilization is to keep the complex, you	11:34:42
4	know, amorphous. And by keeping the complex	11:34:43
5	amorphous, you increase solubility and also	11:34:48
6	increase bioavailability.	11:34:52
7	The down side, of course, is that	11:34:53
8	with these kind of things it -- you -- they	11:34:56
9	may become unstable. But the good thing	11:34:59
10	about cyclodextrin is it actually does	11:35:05
11	stabilize the molecule. So, you know, we did	11:35:08
12	all of that work.	11:35:10
13	Q. Thank you.	11:35:15
14	You started that -- your answer with,	11:35:18
15	"We went and actually tried to make it in the	11:35:21
16	lab."	11:35:23
17	When you say, "We," who are you	11:35:23
18	referring to?	11:35:25
19	A. I was -- I never take credit -- a hundred	11:35:26
20	percent credit for anything, so I say, "We."	11:35:29
21	I never use the word "I."	11:35:34
22	Q. Okay. So other than yourself, who was	11:35:36

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1	involved with --	11:35:38
2	A. I -- I couldn't --	11:35:40
3	Q. -- taking --	11:35:42
4	A. -- I couldn't recall at this moment in time.	11:35:42
5	It could have been, you know, scientists who	11:35:46
6	analyzed, for example, the complex. Or, you	11:35:48
7	know, we ran some stability studies, so they	11:35:51
8	could be, you know, somebody running a	11:35:56
9	stability study. I wouldn't know who that	11:35:58
10	person would be.	11:36:00
11	Q. So who did you have in mind when you said,	11:36:01
12	"We"?	11:36:07
13	A. I -- at this point to kind of say, again,	11:36:07
14	that pharmaceutical development is a team	11:36:10
15	game. It's not a one-person game. And I	11:36:14
16	would never take credit for, you know, having	11:36:21
17	done everything myself, no.	11:36:25
18	There are always people behind you,	11:36:28
19	people helping you, and I would never say,	11:36:29
20	you know, I did everything. No, I did not.	11:36:34
21	And I wouldn't -- at this moment in time, I	11:36:39
22	wouldn't know who that other people who	11:36:42

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1	helped would have been. And, actually, I	11:36:44
2	can't recall anybody -- anybody's name, you	11:36:47
3	know, currently.	11:36:51
4	Q. Okay. So when you were talking about	11:36:56
5	your efforts in the lab trying to figure	11:36:59
6	out how to formulate the complex	11:37:03
7	cladribine-cyclodextrin complex, when exactly	11:37:08
8	was all of this happening?	11:37:14
9	MS. PHENG: Objection to form.	11:37:15
10	THE WITNESS: So, again, without	11:37:19
11	having lab books in front of you, it's	11:37:23
12	difficult to say because, you know, just	11:37:25
13	going by recollection of what happened	11:37:28
14	20 years ago. So it must have been, you	11:37:32
15	know, I would say either late 2002, 2003,	11:37:35
16	that time.	11:37:40
17	BY MR. LIU:	11:37:48
18	Q. What did Dr. Bodor specifically contribute to	11:37:48
19	the complex cladribine-cyclodextrin complex	11:37:52
20	described in the Bodor PCT?	11:37:57
21	MS. PHENG: Objection to form,	11:37:59
22	foundation, scope.	11:38:02

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1	THE WITNESS: I think we covered	11:38:03
2	this earlier. So Dr. Bodor had already done	11:38:05
3	some work on it prior to me getting involved.	11:38:07
4	BY MR. LIU:	11:38:12
5	Q. Do you recall what work he performed on this,	11:38:15
6	on the complex cladribine-cyclodextrin	11:38:17
7	complex?	11:38:20
8	A. I think he had looked at using cyclodextrins	11:38:21
9	with cladribine before I got involved.	11:38:26
10	MR. LIU: Okay. Rachel, can we	11:38:38
11	bring up Tab 3.	11:38:43
12	THE TECHNICIAN: (Complies.)	11:38:47
13	BY MR. LIE:	11:38:47
14	Q. Dr. Dandiker, this is the '415 patent that	11:39:00
15	you referred to in your declaration, correct?	11:39:01
16	A. Yes, I believe so.	11:39:03
17	Q. Okay. And just for the record, this is	11:39:04
18	US Patent Number 8,785,415, and it's	11:39:09
19	Exhibit 2029.	11:39:12
20	If we can -- if you look at the top,	11:39:18
21	this '415 patent names you and Dr. Nicholas	11:39:19
22	Bodor as inventors, correct?	11:39:23

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1	A. Right.	11:39:24
2	Q. And do you stand by the disclosures of	11:39:27
3	the '415 patent?	11:39:31
4	A. Yes.	11:39:32
5	Q. And did you read the '415 patent before it	11:39:32
6	was filed?	11:39:42
7	A. I may have done, I don't know.	11:39:45
8	Q. Did you read the '415 patent before you	11:39:49
9	signed your declaration in this case?	11:39:53
10	A. As I say, I may have done. I can't recall	11:39:58
11	reading it. I do remember reading the	11:40:00
12	claims.	11:40:02
13	Q. And when do you remember -- when did this --	11:40:05
14	when were you reading the claims?	11:40:08
15	When did you read the claims? I	11:40:12
16	apologize.	11:40:14
17	A. This was a long time ago. I wouldn't be able	11:40:14
18	to put a date on it.	11:40:18
19	Q. Did you read the '415 patent after Merck	11:40:22
20	retained you in this case?	11:40:26
21	A. Yeah, I scan read it.	11:40:30
22	Q. When was the last time you read the '415	11:40:51

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1	patent prior to Merck retaining you in this	11:40:54
2	proceeding?	11:40:56
3	A. It must have been when it was being drafted.	11:40:57
4	Q. Dr. Dandiker -- sorry.	11:41:07
5	A. As I said earlier, there was no reason for me	11:41:08
6	to read it afterwards.	11:41:11
7	Q. Okay. Dr. Dandiker, the '415 patent is	11:41:15
8	assigned to Ares Trading S.A.	11:41:19
9	Do you see that?	11:41:22
10	A. Yeah.	11:41:22
11	Q. Did you receive any financial compensation	11:41:23
12	for this assignment?	11:41:26
13	A. No.	11:41:28
14	Q. Did you receive any awards or accolades or	11:41:30
15	plaques for this assignment?	11:41:33
16	A. No.	11:41:35
17	Q. Dr. Dandiker, who drafted the '415 patent?	11:41:41
18	A. I don't know actually. As I said, I was --	11:41:45
19	it was done by counsel, but I just don't know	11:41:47
20	who.	11:41:51
21	Q. Do you know if it was in-house counsel at	11:41:51
22	IVAX?	11:41:54

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1	A. I don't know. As I said, I did speak with	11:41:57
2	somebody. I didn't know -- I do not know	11:42:00
3	whether they were in-house or they were	11:42:02
4	specifically brought in for this. I don't	11:42:04
5	know.	11:42:08
6	Q. Did you -- who did you communicate --	11:42:08
7	A. I just don't know --	11:42:11
8	Q. Sorry. Go ahead.	11:42:14
9	A. I just don't know their name.	11:42:15
10	Q. Okay. Did you communicate with counsel while	11:42:17
11	the '415 patent was being drafted?	11:42:21
12	MS. PHENG: I just want to caution	11:42:23
13	the witness not to reveal the substance of	11:42:25
14	any communications with counsel, but you may	11:42:27
15	answer.	11:42:29
16	THE WITNESS: I -- like I said,	11:42:29
17	the only time I spoke to anybody or to	11:42:35
18	counsel was when I was at IVAX. After that,	11:42:38
19	I have not spoken to anybody. So, you know,	11:42:41
20	it must have been 2004 or before.	11:42:45
21	MR. LIU: Okay, Rachel, you can	11:42:58
22	take that down.	11:42:59

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1	THE TECHNICIAN: (Complies.)	11:43:00
2	MR. LIU: Rachel, can you bring up	11:43:05
3	Tab 9, please.	11:43:07
4	THE TECHNICIAN: (Complies.)	11:43:08
5	BY MR. LIU:	11:43:23
6	Q. Dr. Dandiker, this is the file history for	11:43:23
7	the '415 patent, and it's been previously	11:43:25
8	marked as Hopewell Exhibit 1058.	11:43:28
9	A. All right.	11:43:30
10	MS. PHENG: I just want to object	11:43:31
11	to this exhibit, as my -- as I understand it	11:43:32
12	hasn't been produced and it hasn't -- wasn't	11:43:35
13	a part of the petition. So I object to the	11:43:38
14	extent there are any arguments that are based	11:43:40
15	on this particular exhibit.	11:43:42
16	BY MR. LIU:	11:43:45
17	Q. Dr. Dandiker, have you seen the whole	11:43:45
18	prosecution history for the '415 patent	11:43:48
19	before?	11:43:50
20	A. I have not.	11:43:51
21	Q. Have you read through the prosecution history	11:43:53
22	for the '415 patent?	11:43:58

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1	MS. PHENG: Objection to	11:43:59
2	foundation, scope, relevance.	11:44:00
3	THE WITNESS: I have not seen it,	11:44:03
4	so I would have not read through it.	11:44:04
5	MR. LIU: Let's go to PDF page 9	11:44:08
6	of 444 of the PDF.	11:44:10
7	THE TECHNICIAN: (Complies.)	11:44:10
8	MR. LIU: I just want to clarify	11:44:21
9	on the record that this file history, which	11:44:23
10	is Exhibit 1058, has been produced during	11:44:26
11	this -- during Dr. Bodor's deposition, so it	11:44:29
12	has been produced to patent owner.	11:44:32
13	MS. PHENG: I maintain my	11:44:36
14	objection that it wasn't part of the	11:44:38
15	petition. And to the extent there are any	11:44:40
16	arguments based on it, we hold our objection.	11:44:42
17	MR. LIU: Rachel, to the extent	11:44:51
18	that you can, could you possibly put in the	11:44:53
19	link this copy, which should be available in	11:44:55
20	the download link that Planet Depos provided	11:44:58
21	to counsel showing that the file history for	11:45:02
22	the '415 patent has been produced and labeled	11:45:04

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1	as Exhibit 1058.	11:45:09
2	BY MR. LIU:	11:45:17
3	Q. Okay. Now that we're on page --	11:45:17
4	THE TECHNICIAN: I'm sorry -- I'm	11:45:20
5	sorry, did you just want the file in the	11:45:23
6	Chat? I have --	11:45:26
7	MR. LIU: Sure. Can you please	11:45:26
8	put the -- sure, can you please put file in	11:45:28
9	the Chat and also provide the download link	11:45:29
10	again to counsel, if she has not received	11:45:31
11	this link, the download link.	11:45:35
12	MS. PHENG: Yeah, I don't believe	11:45:38
13	we have received the download link, so if you	11:45:38
14	could please send that, either put it in the	11:45:41
15	Chat or send it to my email.	11:45:45
16	THE TECHNICIAN: Okay. Sure. The	11:45:45
17	download link to all the exhibits that you	11:45:45
18	uploaded previously?	11:45:45
19	MR. LIU: Yes. I just want the	11:45:53
20	download link for any exhibit that I've	11:45:54
21	already introduced --	11:45:56
22	THE TECHNICIAN: Oh, okay.	11:45:56

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1	MR. LIU: -- in the deposition so	11:45:57
2	far, not all of the exhibits that I've	11:45:58
3	already uploaded. It should just be --	11:46:00
4	THE TECHNICIAN: Okay. Thank you	11:46:03
5	for that.	11:46:03
6	MR. LIU: Yes, thank you.	11:46:04
7	THE TECHNICIAN: Yup.	11:46:06
8	MR. LIU: Mary, were you able to	11:46:28
9	open the already-produced Exhibit 1058?	11:46:29
10	MS. PHENG: In the process. I	11:46:31
11	think I'm still waiting on the link for all	11:46:33
12	the exhibits that have been introduced, but	11:46:36
13	I'm in the process of downloading 1058.	11:46:39
14	MR. LIU: Okay. But you've	11:46:44
15	received the already-produced Bodor	11:46:46
16	Exhibit 1058, correct?	11:46:48
17	MS. PHENG: I'm in the process of	11:46:50
18	downloading it.	11:46:51
19	MR. LIU: Let me know --	11:46:51
20	MS. PHENG: I have received access	11:46:52
21	to it, but it's still downloading.	11:46:53
22	MR. LIU: Okay.	11:46:56

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1	MS. PHENG: I don't want to hold	11:46:56
2	up the questioning, though, so I can follow	11:46:57
3	along with the exhibit before us, you know,	11:46:59
4	subject to my objection, again, that it	11:47:05
5	wasn't produced with the petition, and to the	11:47:07
6	extent there are any new arguments based on	11:47:09
7	it, we object.	11:47:11
8	MR. LIU: Okay. Okay. I just	11:47:19
9	want to clarify that this exhibit was	11:47:22
10	produced -- was provided to the court	11:47:24
11	reporter that you hired with Planet Depos for	11:47:29
12	Dr. Bodor's deposition yesterday, but I'm	11:47:30
13	just going to move on.	11:47:33
14	MS. PHENG: I think that's clear	11:47:34
15	on the record.	11:47:35
16	MR. LIU: Okay. Great.	11:47:40
17	BY MR. LIU:	11:47:42
18	Q. All right. Dr. Dandiker, as we can see here	11:47:42
19	on page 9, we see a declaration from the	11:47:45
20	below named inventors of the '415 patent.	11:47:47
21	Do you see that?	11:47:49
22	A. Sorry, this is on the -- in the declaration?	11:47:50

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1	Q. Nope. I'm talking about the declaration on	11:47:56
2	page 9. Do you see that it says, "Combined	11:47:59
3	Declaration and Power of Attorney For Utility	11:48:05
4	or Design Patent Application"?	11:48:05
5	Do you see that's the title of	11:48:08
6	page 9?	11:48:13
7	A. Yes.	11:48:14
8	Q. Do you see that?	11:48:15
9	A. Yeah.	11:48:15
10	Q. Great.	11:48:16
11	Now, so this is on page 9 of	11:48:18
12	Exhibit 1058. And below that title of	11:48:22
13	Exhibit 1058, you see, "As a below-named	11:48:28
14	inventor, I hereby declare that"?	11:48:31
15	Do you see that?	11:48:34
16	A. Yes.	11:48:34
17	Q. Dr. Dandiker, do you see that?	11:48:37
18	A. Yeah, yeah.	11:48:39
19	Q. Okay. And then below that, do you see the	11:48:39
20	sentence, "I believe I am the original, first	11:48:44
21	and sole inventor, if only one name is listed	11:48:49
22	below, or an original, first and joint	11:48:51

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1	inventor if plural names are listed below, of	11:48:53
2	the subject matter which is claimed and for	11:48:58
3	which a patent is sought on the invention	11:49:00
4	entitled"?	11:49:01
5	Do you see that?	11:49:02
6	A. Yup, yup.	11:49:03
7	Q. All right. If we can flip to the next page,	11:49:05
8	PDF page 10 of Exhibit 1058.	11:49:08
9	So on Exhibit 1058, page 10, do you	11:49:19
10	see a table of inventors?	11:49:23
11	Do you see that?	11:49:24
12	A. Right. Yup.	11:49:25
13	Q. Do you see your name listed?	11:49:26
14	A. Yes.	11:49:29
15	Q. And that's also your signature, correct?	11:49:29
16	A. Yeah.	11:49:34
17	Q. Okay. Great.	11:49:35
18	MR. LIU: You can take that down.	11:49:39
19	THE TECHNICIAN: (Complies.)	11:49:40
20	MR. LIU: I think this is a good	11:49:43
21	time for a break.	11:49:44
22	MS. PHENG: That sounds great to	11:49:46

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1	us.	11:49:47
2	THE WITNESS: Okay.	11:49:47
3	THE VIDEOGRAPHER: Okay. We are	11:49:48
4	going off the record. The time is 11:50.	11:49:50
5	(Lunch recess.)	11:49:54
6	THE VIDEOGRAPHER: We are back on	12:36:58
7	the record. The time is 12:37.	12:37:01
8	BY MR. LIU:	12:37:06
9	Q. Welcome back, Dr. Dandiker.	12:37:06
10	A. Okay.	12:37:08
11	Q. Did you speak with counsel regarding the	12:37:09
12	substance of your testimony today during the	12:37:14
13	break?	12:37:15
14	A. No.	12:37:16
15	MR. LIU: Rachel, can you please	12:37:21
16	pull up Tab 4.	12:37:24
17	THE TECHNICIAN: (Complies.)	12:37:25
18	BY MR. LIU:	12:37:37
19	Q. Dr. Dandiker, this is Exhibit 2069, which is	12:37:38
20	US Patent Number 7,888,328.	12:37:41
21	A. Right.	12:37:44
22	Q. Dr. Dandiker, this -- the '328 patent names	12:37:44

1	you and Dr. Nicholas Bodor as inventors,	12:37:51
2	correct?	12:37:54
3	A. Yeah. Yeah, that's right.	12:37:55
4	Q. And do you stand by the disclosures of	12:37:57
5	the '328 patent?	12:38:00
6	A. Yes.	12:38:05
7	Q. Dr. Dandiker, did you read the '328 patent	12:38:05
8	before it was filed?	12:38:11
9	A. I may have done. Again, it was a long time	12:38:16
10	ago.	12:38:19
11	Q. Did you read the '328 patent before you	12:38:21
12	signed your declaration in this proceeding?	12:38:26
13	A. As I mentioned earlier, I recall reading the	12:38:29
14	claims. I may have just scan read the rest.	12:38:32
15	Q. Is there any reason to doubt that you read	12:38:38
16	it -- read the '328 patent before it was	12:38:42
17	filed?	12:38:45
18	A. Say that again.	12:38:49
19	Q. Is there any reason to doubt that you read	12:38:50
20	the '328 patent before it was filed?	12:38:52
21	A. I read the claims, and the rest I may have	12:38:57
22	just scan read it.	12:39:00

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1	Q. And this was before it was -- the '328 patent	12:39:04
2	was filed, correct?	12:39:09
3	A. Yeah, because my -- as I said earlier, my,	12:39:10
4	kind of, interest really is in the claims.	12:39:12
5	Q. Okay. And you said that you read the '328	12:39:25
6	patent -- oh, actually, strike that.	12:39:30
7	Did you read the '328 patent after	12:39:32
8	Merck retained you in this proceeding?	12:39:34
9	A. Very briefly. I mean, I think read the other	12:39:36
10	one first. It gets to be boring, because	12:39:44
11	it's a bit repetitious. So I didn't, kind	12:39:46
12	of -- you know, I didn't pay too much	12:39:50
13	attention to it.	12:39:52
14	Q. Okay. So you do recall reading the '328	12:39:54
15	patent after Merck retained you and before	12:39:58
16	you signed your declaration in this	12:40:00
17	proceeding, correct?	12:40:03
18	A. Yeah, but I would say very briefly.	12:40:04
19	Q. The '328 patent is assigned to	12:40:14
20	Ares Trading S.A.	12:40:17
21	A. Right.	12:40:18
22	Q. Did you receive any financial compensation	12:40:18

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1	for this assignment?	12:40:21
2	A. No.	12:40:26
3	Q. Did you receive any awards or accolades or	12:40:26
4	plaques, for example --	12:40:30
5	A. No.	12:40:31
6	Q. -- in recognition?	12:40:32
7	A. No, nothing.	12:40:33
8	Q. Dr. Dandiker, who drafted the '328 patent?	12:40:36
9	MS. PHENG: Objection; calls for	12:40:41
10	privilege. I just caution the witness not to	12:40:43
11	reveal the substance of any communication	12:40:46
12	with counsel.	12:40:48
13	THE WITNESS: Yeah, I -- you know,	12:40:48
14	I can't recall who drafted it. I can't	12:40:52
15	recall the counsel's name, but it was drafted	12:40:53
16	by counsel.	12:40:55
17	BY MR. LIU:	12:40:56
18	Q. Did you have any role in drafting the '328	12:40:57
19	patent?	12:41:00
20	MS. PHENG: Same objection.	12:41:01
21	THE WITNESS: No, I did not. I	12:41:04
22	provided the information, but I did not draft	12:41:07

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1	it.	12:41:09
2	BY MR. LIU:	12:41:09
3	Q. So you did communicate with counsel while	12:41:09
4	the '328 patent was being drafted, correct?	12:41:11
5	A. It --	12:41:15
6	MS. PHENG: Same objection.	12:41:17
7	You can answer yes or no.	12:41:18
8	THE WITNESS: Yeah, I mean, you	12:41:20
9	know, what I want to also just clarify is	12:41:24
10	that I left IVAX in 2004. After that, I have	12:41:29
11	had no communication on any of these things	12:41:34
12	regarding, you know, this patent application	12:41:39
13	or the cladribine project at all.	12:41:43
14	So anything which was done prior to	12:41:46
15	my leaving IVAX, I may have contributed to.	12:41:49
16	Afterwards, there was certainly no	12:41:54
17	communication between myself and them.	12:41:57
18	So, you know, when you start looking	12:42:00
19	at dates here, it says PCT filed, you know,	12:42:02
20	March 26th. It was filed after I left.	12:42:08
21	BY MR. LIU:	12:42:21
22	Q. But you don't recall who you communicated	12:42:22

1	with in the drafting of the '328 patent,	12:42:24
2	correct?	12:42:27
3	A. Yeah, so again just to clarify, this	12:42:29
4	application was filed after I left the	12:42:32
5	company. And so prior to that, I can't	12:42:33
6	recall who I communicated with.	12:42:40
7	MR. LIU: Okay. We can take that	12:42:52
8	down.	12:42:54
9	THE TECHNICIAN: (Complies.)	12:42:54
10	MR. LIU: Rachel, can you bring up	12:42:57
11	Tab 10, please.	12:43:00
12	THE TECHNICIAN: (Complies.)	12:43:02
13	BY MR. LIU:	12:43:11
14	Q. Dr. Dandiker, this is the file history for	12:43:11
15	US Patent Number 7,888,328, which has been	12:43:13
16	previously marked as Hopewell's Exhibit 1057	12:43:17
17	in these proceedings.	12:43:22
18	MR. LIU: And, Counsel, you can	12:43:25
19	download this marked exhibit in the download	12:43:26
20	link, but let us know if you need Rachel to	12:43:30
21	send it through the Chat.	12:43:35
22	MS. PHENG: Okay. Just give me a	12:43:36

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1	second just to make sure it's appeared on	12:43:38
2	the --	12:43:41
3	MR. LIU: Sure. Let me know when	12:43:44
4	you're ready.	12:43:45
5	THE TECHNICIAN: It's just taking	12:43:45
6	a minute to upload. It's a big file.	12:43:53
7	MS. PHENG: I just want to note,	12:43:53
8	similar to my prior objection, that this was	12:43:55
9	not produced prior to the petition, and we	12:43:57
10	object to any new arguments that are based on	12:43:59
11	this exhibit.	12:44:02
12	MR. LIU: Okay. I will note that	12:44:03
13	this Exhibit 1057 was introduced and marked	12:44:04
14	at Dr. Bodor's deposition yesterday.	12:44:07
15	Counsel, do you --	12:44:15
16	MS. PHENG: And I have the exhibit	12:44:15
17	as well. Sorry.	12:44:18
18	MR. LIU: Okay. Great.	12:44:19
19	BY MR. LIU:	12:44:20
20	Q. Dr. Dandiker, have you seen the prosecution	12:44:20
21	history for your '328 patent before?	12:44:23
22	A. I have not.	12:44:26

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1	MR. LIU: Okay. Rachel, can we	12:44:31
2	please go to PDF page 159.	12:44:32
3	THE TECHNICIAN: (Complies.)	12:44:35
4	BY MR. LIU:	12:44:47
5	Q. So Dr. Dandiker, as with the '415 patent file	12:44:47
6	history, we see a declaration from the	12:44:52
7	below-named inventors of the '328 patent?	12:44:54
8	A. Right.	12:44:57
9	Q. Do you see that?	12:44:57
10	A. Yup.	12:44:58
11	Q. Okay. Do you see where it says, "I believe	12:45:02
12	I'm the original, first and either sole or	12:45:04
13	joint inventor of the subject matter which is	12:45:06
14	claimed and for which a patent is sought"?	12:45:08
15	A. Yup.	12:45:12
16	MR. LIU: Okay. Rachel, can you	12:45:13
17	please flip to the next page.	12:45:14
18	THE TECHNICIAN: (Complies.)	12:45:16
19	BY MR. LIU:	12:45:22
20	Q. Dr. Dandiker, do you see a table of	12:45:22
21	inventors --	12:45:24
22	A. Yes.	12:45:24

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1	Q. -- on this page?	12:45:25
2	A. Yup.	12:45:26
3	Q. Okay. And it shows your name as a listed	12:45:27
4	inventor on Exhibit 1057?	12:45:32
5	A. Yup.	12:45:37
6	Q. And it also -- Exhibit 1057, page 160, also	12:45:38
7	includes your signature, correct?	12:45:45
8	A. Yes.	12:45:46
9	MR. LIU: Okay, Rachel, you can	12:45:49
10	take this down. Thank you.	12:45:50
11	THE TECHNICIAN: (Complies.)	12:45:53
12	BY MR. LIU:	12:45:54
13	Q. Dr. Dandiker, you used the phrase "dosing	12:45:54
14	regimen" throughout your declaration. What	12:45:57
15	did you mean by the term "dosing regimen"?	12:46:00
16	A. And that is actually not my term. Dosing	12:46:04
17	regimen is not within my expertise, so that	12:46:17
18	is -- that is, you know, my -- that is not a	12:46:24
19	formulation-related term.	12:46:30
20	Q. You state that the term "dosing regimen" is	12:46:35
21	not a term that you use. So whose term is	12:46:47
22	it?	12:46:52

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1	A. It is not a formulation term.	12:46:52
2	Q. Do you have any understanding of what a	12:46:58
3	dosing regimen is?	12:47:00
4	A. Yes. Yeah. I mean, I think most people	12:47:04
5	would have.	12:47:08
6	Q. And what is that understanding?	12:47:13
7	A. As to how something ought to be dosed, right,	12:47:16
8	whether you take an aspirin tablet or	12:47:21
9	anything else.	12:47:22
10	Q. And is that the understanding that you	12:47:30
11	applied in your declaration when you used the	12:47:32
12	term "dosing regimen"?	12:47:37
13	A. As I say, it is not my term. It is, you	12:47:38
14	know, not my area of expertise. So, you	12:47:41
15	know, my area of expertise is formulation.	12:47:45
16	And, you know, that is not my term.	12:47:49
17	Q. But you agree that you used the term "dosing	12:47:58
18	regimen" throughout your declaration that you	12:48:01
19	submitted in these proceedings, correct?	12:48:03
20	A. Yes. So it is in the declaration. But on	12:48:04
21	the declaration I also say that, you know, it	12:48:07
22	is not my area of expertise.	12:48:13

1 Q. So what did you mean when you used the term 12:48:31
2 "dosing regimen" as it is used in your 12:48:34
3 declaration? 12:48:36

4 A. Actually, I don't know where that is called 12:48:38
5 into the patent application, but the 12:48:46
6 declaration is based on what is actually on 12:48:48
7 the patent application, which is what is in 12:48:49
8 the patent application. 12:48:53

9 So, basically, in the declaration I 12:48:54
10 am clarifying that, you know, it is not my 12:48:58
11 area of expertise and, you know, I am not 12:49:01
12 responsible or the inventor of the dosing 12:49:04
13 regimen. 12:49:07

14 MR. LIU: Rachel, can we bring up 12:49:15
15 Tab 5, please. 12:49:18

16 THE TECHNICIAN: (Complies.) 12:49:18

17 MR. LIU: Actually, sorry, Rachel, 12:49:26
18 before we -- can you take that down. 12:49:28

19 THE TECHNICIAN: (Complies.) 12:49:30

20 BY MR. LIU: 12:49:32

21 Q. What is the difference between a dosing 12:49:32
22 regimen and a formulation? 12:49:34

1	MS. PHENG: Objection to form,	12:49:37
2	scope, relevance.	12:49:39
3	THE WITNESS: So a formulation is	12:49:45
4	where you take the drug and you take a number	12:49:47
5	of, let's say, chemical powders, put them	12:49:53
6	together to give you the desired release	12:49:58
7	from, let's say, a tablet as an example. So	12:50:01
8	your formulation is what are -- what we call	12:50:04
9	excipients that combine with the drug, and	12:50:08
10	does that give you the desired release of the	12:50:18
11	drug.	12:50:19
12	So a drug could be, you know, an	12:50:19
13	immediate-release tablet, it could be an	12:50:21
14	extended-release tablet, it could be an	12:50:23
15	injectable, it could be a patch, it could be	12:50:26
16	anything.	12:50:28
17	But a formulation is how you put	12:50:29
18	together those excipients to give you the	12:50:33
19	desired release.	12:50:38
20	A dosing regimen is actually	12:50:38
21	something very different, which is how would	12:50:41
22	you then take that and apply it clinically.	12:50:42

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1	So to kind of reduce it to, kind of,	12:50:46
2	a couple of words, so one is related to, you	12:50:52
3	know, how you put chemicals together, and the	12:50:57
4	other is related to how you administer it	12:51:00
5	clinically.	12:51:03
6	So there's chemistry and clinical,	12:51:05
7	kind of, you know, applications.	12:51:08
8	BY MR. LIU:	12:51:14
9	Q. So when you say a dosing regimen is actually	12:51:15
10	something different, which is how you would	12:51:18
11	then take that and apply it clinically, did	12:51:21
12	you mean that formulation?	12:51:26
13	MS. PHENG: Objection to form.	12:51:29
14	THE WITNESS: No. Again, I just	12:51:35
15	want to say that is not a term I can assign	12:51:36
16	to myself, because I have no expertise in	12:51:39
17	dosing regimen and, you know, as I mentioned	12:51:43
18	in my declaration that I'm not the inventor	12:51:49
19	of the dosing regimen. The patent is a	12:51:52
20	formulation patent, and that is -- you know,	12:51:56
21	that is what my expertise is.	12:52:01
22	BY MR. LIU:	12:52:05

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1	Q. I completely understand that. I was just	12:52:05
2	understanding what you actually just	12:52:07
3	testified to. So when you said that a dosing	12:52:09
4	regimen is something different and is how I	12:52:14
5	would take that, I was just wondering what	12:52:18
6	you meant when you said that.	12:52:21
7	A. Yeah, that's kind of my, as I said,	12:52:22
8	colloquial explanation. I would not take	12:52:25
9	that as science, right. If you look in	12:52:28
10	textbooks, it'll be a different definition.	12:52:32
11	Q. Oh, absolutely. I was just -- I'm just	12:52:34
12	trying to understand what you meant when you	12:52:36
13	said, "Take that."	12:52:38
14	A. Yeah, so the formulation is when you put a	12:52:38
15	drug with a number of chemicals and try to	12:52:43
16	get a desired release. And a dosing regimen	12:52:46
17	is when you take your, let's say, finished	12:52:49
18	dosage form and determine how that should be	12:52:53
19	dosed clinically.	12:52:57
20	Q. And when you say -- oh, sorry. Go ahead.	12:52:59
21	A. Yeah, how that should be dosed clinically to	12:53:02
22	give you the desired outcome, clinical	12:53:05

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1	outcome.	12:53:07
2	Q. And when you say, "Dosage form," that	12:53:08
3	includes the formulation, correct?	12:53:10
4	A. Yeah, a dosage form could be, you know,	12:53:14
5	anything, tablet, capsule, a patch, could be	12:53:17
6	injectable. But yes.	12:53:19
7	MR. LIU: Rachel, can you please	12:53:33
8	bring up Tab 5, please.	12:53:35
9	THE TECHNICIAN: (Complies.)	12:53:37
10	BY MR. LIU:	12:53:37
11	Q. Dr. Dandiker --	12:53:51
12	MS. PHENG: Tyler --	12:53:51
13	MR. LIU: Yes?	12:53:51
14	MS. PHENG: Just before we -- just	12:53:54
15	before you start, I just want to confirm that	12:53:55
16	this is the redacted copy that our -- one of	12:53:57
17	our attorneys served on you, I believe,	12:54:01
18	yesterday?	12:54:03
19	MR. LIU: Yes. I just want to say	12:54:04
20	on the record that counsel for patent owner	12:54:05
21	only provided the redacted version of this	12:54:08
22	exhibit, which is Exhibit 2050, on Thursday	12:54:10

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1	morning, and we are now using this redacted	12:54:12
2	version of Exhibit 2050 to question	12:54:15
3	Dr. Dandiker.	12:54:18
4	MS. PHENG: Okay. I appreciate	12:54:19
5	the clarity. Thank you.	12:54:20
6	BY MR. LIU:	12:54:25
7	Q. Dr. Dandiker, do you recognize this document?	12:54:25
8	A. I do.	12:54:28
9	Q. Dr. Dandiker, when was the first time you saw	12:54:29
10	this document?	12:54:35
11	A. I saw it more recently when it was shared	12:54:35
12	with me by my counsel, but I may have seen it	12:54:40
13	many years ago when I was at IVAX too. But	12:54:45
14	if I had not seen it recently, I would -- I	12:54:50
15	would probably say I don't know about it.	12:54:54
16	But now I see it again, I do recall having	12:54:57
17	seen it.	12:55:00
18	Q. Okay. So you do recall having seen it?	12:55:04
19	A. Yeah.	12:55:06
20	Q. Okay. And when would that be? When was the	12:55:07
21	last time you saw this document prior to	12:55:15
22	Merck retaining you in this case?	12:55:17

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1	A. It must have been when it's dated, which is	12:55:18
2	2003.	12:55:22
3	Q. So are you assuming that you saw this	12:55:31
4	document or do you have a specific	12:55:33
5	recollection of seeing this document in 2003?	12:55:35
6	MS. PHENG: Objection to form.	12:55:39
7	THE WITNESS: I am assuming that,	12:55:40
8	because my -- you know, it is referring to a	12:55:42
9	meeting I attended in 2003. So, you know,	12:55:48
10	I'm assuming that I've -- and I have no	12:55:51
11	reason to doubt the minutes of that meeting,	12:55:55
12	which is what this document is.	12:55:58
13	BY MR. LIU:	12:56:15
14	Q. Dr. Dandiker, did you review a draft of this	12:56:16
15	document?	12:56:19
16	A. No. I mean, these are minutes, from what I	12:56:22
17	recall, written by somebody at Serono.	12:56:26
18	Q. You have no specific -- sorry, go ahead. Did	12:56:31
19	you finish?	12:56:34
20	A. Yeah. So, you know, in any meeting you get	12:56:34
21	minutes, you don't -- you don't start	12:56:40
22	changing the minutes. So in this case, you	12:56:45

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1	know, the minutes, as I recall, were from	12:56:47
2	Serono, and they document the meeting.	12:56:49
3	Q. But you don't have a specific recollection of	12:56:55
4	reviewing any version of this document,	12:56:58
5	correct?	12:57:02
6	A. That is correct.	12:57:02
7	MS. PHENG: Objection to form.	12:57:02
8	THE WITNESS: Sorry. Yes, that is	12:57:03
9	correct.	12:57:06
10	MR. LIU: Rachel, can you scroll	12:57:22
11	down from this first page.	12:57:23
12	THE TECHNICIAN: (Complies.)	12:57:23
13	BY MR. LIU:	12:57:23
14	Q. Dr. Dandiker, do you see on bottom right of	12:57:25
15	this document it says, "Draft minutes"?	12:57:27
16	Do you see that?	12:57:30
17	A. Yes.	12:57:31
18	Q. Do you know if this was the final version of	12:57:31
19	this document?	12:57:33
20	A. I don't. Also, I mean, you know, many times	12:57:34
21	people put draft on everything, right, so I	12:57:44
22	don't know whether there were another set of	12:57:50

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1	minutes issued after this.	12:57:53
2	Q. Dr. Dandiker, what was the purpose of this	12:58:02
3	document?	12:58:08
4	MS. PHENG: Objection to form,	12:58:08
5	foundation, relevance.	12:58:09
6	THE WITNESS: Sorry, can you	12:58:12
7	repeat the question again?	12:58:13
8	BY MR. LIU:	12:58:16
9	Q. I'm going to ask a different question.	12:58:17
10	Dr. Dandiker, do you recall receiving	12:58:18
11	a copy of this document?	12:58:21
12	A. Yeah. Yeah, I do. I do kind of -- having	12:58:25
13	seen the minutes, I do recall, you know,	12:58:31
14	having seen it before and having read it.	12:58:34
15	Q. Do you recall when you received this	12:58:37
16	document, a copy of this document?	12:58:39
17	A. It must have been sometime in 2003. And that	12:58:41
18	is an assumption based on the dates on the	12:58:45
19	document.	12:58:47
20	Q. Okay. And how did you receive a copy of this	12:58:49
21	document before Merck retained you in this	12:58:53
22	proceeding?	12:58:57

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1	A. I don't know. I don't know whether a hard	12:58:59
2	copy was sent to me or an email was sent to	12:59:01
3	me. I just don't know.	12:59:04
4	Q. What is the basis for your recollection that	12:59:09
5	you received a copy of this document?	12:59:13
6	A. It's because it's a meeting I attended, which	12:59:15
7	I do remember attending, and these are	12:59:18
8	minutes of that meeting. So my inference is	12:59:20
9	that if I attended a meeting, somebody sends	12:59:24
10	me the minutes, that's kind of documenting,	12:59:27
11	you know, the meeting per se. So my	12:59:32
12	assumption is that if I attended a meeting	12:59:35
13	and somebody sends me the minutes, then, you	12:59:37
14	know, I have no reason to doubt otherwise.	12:59:39
15	Q. Dr. Dandiker, what was the purpose of this	12:59:48
16	document?	12:59:50
17	A. The purpose of this document really --	12:59:52
18	MS. PHENG: Sorry, give me a	12:59:55
19	chance to object.	12:59:56
20	Objection to form, scope, foundation,	12:59:57
21	relevance.	13:00:02
22	You may answer.	13:00:05

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1	THE WITNESS: Yeah, I mean, I --	13:00:06
2	if I rephrase your question, I mean, the	13:00:08
3	purpose of the document, of course, is to	13:00:12
4	document the meeting. But the wider purpose	13:00:13
5	is to exchange information between the two	13:00:19
6	organizations on the project. I mean, that	13:00:21
7	is the purpose of the meeting. The purpose	13:00:23
8	of the document is to document that.	13:00:25
9	BY MR. LIU:	13:00:32
10	Q. Who wrote this document?	13:00:32
11	MS. PHENG: Same objection.	13:00:35
12	THE WITNESS: I don't know. I	13:00:37
13	think if I scroll down, there must be	13:00:38
14	somewhere something as to who wrote it.	13:00:41
15	Generally speaking, in most	13:00:45
16	organizations, the person which was the	13:00:46
17	minutes are is usually the project manager.	13:00:51
18	BY MR. LIU:	13:00:55
19	Q. Do you recall who the project manager was?	13:00:55
20	A. I would have to look through the document to	13:00:57
21	find that out.	13:01:00
22	Q. Do you recall if it was someone from IVAX or	13:01:02

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1	someone from Serono who wrote this document?	13:01:06
2	A. Oh, it is somebody from Serono. It is not	13:01:10
3	somebody from IVAX. There were only two of	13:01:13
4	us from IVAX at this meeting, and, you know,	13:01:16
5	I don't think we wrote it. I certainly	13:01:21
6	didn't, and I don't think Dr. Marcus did.	13:01:25
7	Q. And how were you able to recall that it was	13:01:29
8	definitely someone from Serono as opposed to	13:01:32
9	someone from IVAX?	13:01:34
10	A. For us, for somebody from IVAX, it would be	13:01:36
11	very difficult to write this set of minutes,	13:01:40
12	because there's a -- you know, as we go	13:01:42
13	through the remainder of the document, there	13:01:45
14	is a discussion on the clinical piece which	13:01:47
15	really has to come from Serono.	13:01:52
16	But I think, ultimately, that if one	13:02:01
17	were to dig hard enough, you'd find out, you	13:02:08
18	know, who wrote -- who actually wrote the	13:02:10
19	minutes. But my recollection is it's nobody	13:02:12
20	from IVAX.	13:02:15
21	Q. Has IVAX -- did IVAX -- did Serono provide	13:02:22
22	meeting minutes to you from other meetings	13:02:26

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1	between IVAX and Serono?	13:02:30
2	MS. PHENG: Objection to form.	13:02:32
3	THE WITNESS: I kind of don't	13:02:34
4	recall. And this particular meeting, you	13:02:36
5	know, was actually, if anything, you know, a	13:02:41
6	bit of a special meeting where, you know,	13:02:46
7	people are flying from all over the place to	13:02:48
8	Amsterdam for a meeting, and that is not a	13:02:50
9	usual occurrence.	13:02:56
10	So there would be many other, you	13:02:57
11	know, communication forums where we'd speak	13:03:00
12	on the phone or, you know, by email or so on	13:03:03
13	and so forth on a day-to-day basis. But this	13:03:08
14	is really to take stock of the project.	13:03:11
15	And then if you look at the minutes,	13:03:13
16	they start with, for example, marketing and	13:03:15
17	global positioning. And this is the first	13:03:20
18	time, actually, I was exposed to this in	13:03:23
19	terms of, you know, how Serono even think of	13:03:28
20	marketing this product.	13:03:31
21	So as I say, it is not a -- it is not	13:03:34
22	usually how -- how this -- how the meetings	13:03:39

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1	were done.	13:03:42
2	BY MR. LIU:	13:03:46
3	Q. So is this the only meeting that you recall	13:03:46
4	where people were flying from all over the	13:03:49
5	place to another location between IVAX and	13:03:51
6	Serono?	13:03:55
7	A. Yes.	13:03:55
8	MS. PHENG: Objection to form,	13:03:56
9	scope, relevance.	13:03:59
10	THE WITNESS: I mean, I -- for me,	13:04:00
11	yes. I mean, I can't speak for other people.	13:04:02
12	There could be other people at IVAX who are	13:04:05
13	meeting Serono. I wouldn't know.	13:04:10
14	BY MR. LIU:	13:04:20
15	Q. So this is the only meeting of its kind that	13:04:22
16	you recall attending and receiving meeting	13:04:24
17	minutes from, correct?	13:04:27
18	A. Yes, yes.	13:04:29
19	Q. Dr. Dandiker, do you --	13:04:30
20	MR. LIU: Can we go to page 2 of	13:04:45
21	this document, of Exhibit 2050.	13:04:48
22	THE TECHNICIAN: (Complies.)	13:04:54

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1	BY MR. LIU:	13:04:54
2	Q. Dr. Dandiker, do you see on the page that	13:04:55
3	there's some pink highlighting?	13:04:57
4	A. Yeah, I mean, is it possible to expand this a	13:04:58
5	bit?	13:05:01
6	Q. Sure.	13:05:03
7	THE TECHNICIAN: (Complies.)	13:05:03
8	THE WITNESS: Yes.	13:05:06
9	BY MR. LIU:	13:05:07
10	Q. Okay. Dr. Dandiker, do you see under,	13:05:07
11	Phase 1 Studies, there are a couple of	13:05:08
12	paragraphs?	13:05:10
13	A. Yes.	13:05:10
14	Q. And the last paragraph before,	13:05:11
15	Screening Phase 1 Update --	13:05:14
16	A. Yes.	13:05:15
17	Q. -- there is some pink highlighting --	13:05:17
18	A. Yes.	13:05:19
19	Q. -- in the bolded text of the Exhibit 2050.	13:05:20
20	Do you see that?	13:05:23
21	A. Yes. Yup.	13:05:23
22	Q. Do you know who made these markings?	13:05:24

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1	A. I have no idea, no. No, it looks like the --	13:05:27
2	you know, they're somebody's personal	13:05:32
3	minutes, but I just don't know who made those	13:05:35
4	markings.	13:05:37
5	Q. So this isn't your copy --	13:05:38
6	A. No --	13:05:40
7	Q. -- of the --	13:05:40
8	A. No, it isn't my copy.	13:05:40
9	Q. And you're unaware who made these annotations	13:05:44
10	on this document --	13:05:47
11	A. Yes, that --	13:05:48
12	Q. -- on this -- okay.	13:05:49
13	A. That's correct.	13:05:52
14	Q. Do you recall if the August -- strike that.	13:05:53
15	So I just want to clarify for the	13:06:08
16	record that you are unaware of whose copy of	13:06:10
17	the August 2003 minutes this came from,	13:06:14
18	correct?	13:06:17
19	A. Yes.	13:06:17
20	Q. If we go back to page 1 of Exhibit 2050,	13:06:17
21	Dr. Dandiker, do you see that there lists	13:06:37
22	Serono participants and IVAX participants at	13:06:41

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1	the top of page 1 of Exhibit 2050?	13:06:46
2	A. Yes.	13:06:49
3	Q. Okay. I want to first take a look at IVAX's	13:06:49
4	participants.	13:06:54
5	A. All right.	13:06:55
6	Q. And we see S. Marcus, which I assume is	13:06:55
7	Steve Marcus, correct?	13:07:00
8	A. Yes.	13:07:01
9	Q. Okay. And there's also Y. Dandiker, which is	13:07:02
10	you, correct?	13:07:06
11	A. Yup.	13:07:06
12	Q. And then there's an individual named	13:07:07
13	D. Weiner, W-E-I-N-E-R?	13:07:09
14	A. Yes.	13:07:14
15	Q. Do you know who this individual is?	13:07:14
16	A. I can't recall actually at this moment in	13:07:16
17	time.	13:07:19
18	Q. So you don't know who this -- who D. Weiner	13:07:22
19	is from IVAX?	13:07:26
20	A. Yeah, I don't really recall, no.	13:07:27
21	Q. Okay. And then by phone it states D. Emma.	13:07:30
22	Do you see that?	13:07:36

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1	A. Yes.	13:07:36
2	Q. And who is D. Emma?	13:07:37
3	A. I believe he was counsel.	13:07:40
4	Q. Okay. And he attended by phone, correct?	13:07:45
5	A. Yes.	13:07:49
6	Q. And what does D stand for?	13:07:53
7	A. I think it's Dennis.	13:07:54
8	Q. Okay. So out of the four individuals from	13:07:58
9	IVAX, Dennis Emma was the only person who	13:08:04
10	attended by phone, correct?	13:08:07
11	A. Yes.	13:08:08
12	Q. And you don't recall D. Weiner attending this	13:08:09
13	meeting?	13:08:15
14	A. I actually don't, because most people I can	13:08:15
15	picture, and somehow I can't picture him.	13:08:18
16	Q. Okay. All right. Let's go to the Serono	13:08:20
17	participants.	13:08:24
18	A. All right.	13:08:25
19	Q. Okay. Let's go to Serono participants.	13:08:25
20	A. Okay.	13:08:38
21	Q. Do you recognize the individuals listed here?	13:08:39
22	A. I recognize some of them. So, for example,	13:08:41

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1	G. Francis, Maria Lopez-Bresnahan, and	13:08:45
2	Dr. Munafo, I do kind of recognize those	13:08:57
3	people.	13:08:58
4	Q. Do you recognize anyone else's name on this	13:08:58
5	page 1 of Exhibit 2050?	13:09:02
6	A. Yeah, I don't. I mean, as I mentioned	13:09:04
7	earlier, I've come across the name Arnaud,	13:09:06
8	is it Arnaud Ythier? But I can't picture	13:09:14
9	what he looks like.	13:09:15
10	Q. Sorry, can you say that person's name again?	13:09:19
11	I just wanted to make sure I heard that it's	13:09:20
12	clear on the record.	13:09:23
13	A. Yeah, it's Ythier, I think -- I don't know	13:09:24
14	how you pronounce it. Y-T-H-I-E-R.	13:09:27
15	Q. Great. Okay.	13:09:31
16	Let's go back to -- you say that you	13:09:32
17	recognize G. Francis, correct?	13:09:36
18	A. Right.	13:09:37
19	Q. And what does G stand for?	13:09:38
20	A. I think it was Gordon.	13:09:40
21	Q. Okay. And how did you know Gordon Francis?	13:09:42
22	A. I think just from the meeting.	13:09:49

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1	Q. And do you recall what Gordon Francis -- what	13:09:51
2	Gordon Francis's role was at this meeting?	13:09:55
3	A. No, I don't really.	13:09:59
4	Q. Do you recall ever communicating with	13:10:02
5	Gordon Francis?	13:10:05
6	A. I don't. But I would also like to qualify	13:10:06
7	that by saying that I don't know whether he	13:10:10
8	was copied on any emails I may have sent or	13:10:13
9	that those were -- or emails sent to me, but	13:10:16
10	I don't recall communicating him -- with him	13:10:21
11	directly.	13:10:25
12	Q. So you don't recall having any discussions	13:10:28
13	with Gordon Francis, correct?	13:10:30
14	A. Yeah, yeah.	13:10:32
15	Q. And besides Gordon Francis, you recall, as	13:10:33
16	we've talked about Dr. Lopez-Bresnahan and	13:10:44
17	Dr. Munafo, correct?	13:10:50
18	A. Yes.	13:10:51
19	Q. And you recognize the name Dr. Ythier,	13:10:51
20	correct?	13:10:53
21	A. I recognize the name, but I'm having	13:10:54
22	difficulty picturing what he looks like.	13:10:56

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1	Q. Okay. And you don't recognize any of the	13:10:58
2	other Serono participants listed here on	13:11:01
3	page 1 of Exhibit 2050, correct?	13:11:04
4	A. Yeah. I mean, they may have been at the	13:11:06
5	meeting, but it may be, you know, the first	13:11:09
6	time they were there or first time I may have	13:11:12
7	seen them. But I don't recall them now.	13:11:15
8	Q. Okay. And I just wanted to clarify for the	13:11:19
9	record that the individual that you recognize	13:11:21
10	the name is spelled Y-T-H-I-E-R, correct?	13:11:24
11	A. Yeah, I just recognize the name.	13:11:32
12	Q. Okay.	13:11:34
13	A. And as I said earlier, it could be just	13:11:35
14	because the name was on something, like these	13:11:37
15	minutes you -- enough times, that you	13:11:40
16	recognize the name. But yes.	13:11:47
17	Q. Thank you.	13:11:48
18	Do you recall anything else about	13:11:57
19	this Mr. Ythier?	13:11:58
20	A. I don't really. I don't.	13:12:02
21	Q. Do you know if this individual named	13:12:25
22	A. Ythier is the Arnaud Ythier that we talked	13:12:27

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1	about earlier?	13:12:33
2	A. I believe so.	13:12:34
3	Q. Okay.	13:12:34
4	MR. LIU: Now, if we could go to	13:12:47
5	page 2 again, Rachel.	13:12:49
6	THE TECHNICIAN: (Complies.)	13:12:50
7	BY MR. LIU:	13:12:51
8	Q. Now, we were just looking at this earlier on	13:12:52
9	the Phase 1 Studies. Do you see that below	13:12:55
10	that it says the discussion leader was	13:12:59
11	Dr. Marcus? Do you see that?	13:13:02
12	A. Yes. Yes, I do.	13:13:04
13	Q. It says S. Marcus, but you agree that it's	13:13:05
14	referring to Steve Marcus, correct?	13:13:09
15	A. Yes.	13:13:10
16	Q. Okay. Now, if we go to the third paragraph	13:13:11
17	with the highlighting, it states, "The team	13:13:20
18	was interested [REDACTED]	13:13:25
19	[REDACTED]	13:13:28
20	[REDACTED]	13:13:32
21	[REDACTED] And that, "[REDACTED]	13:13:34
22	[REDACTED]	13:13:38

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1	[REDACTED]	13:13:40
2	Do you see that?	13:13:42
3	A. Yes, I do.	13:13:42
4	Q. And when it says, "Team," what is being	13:13:46
5	referred to here?	13:13:49
6	MS. PHENG: Objection to form,	13:13:50
7	foundation.	13:13:51
8	THE WITNESS: My belief is that	13:13:52
9	the team is meant by the group of people who	13:13:54
10	are represented at this meeting. So, you	13:13:57
11	know, everybody who is on the -- on this list	13:14:00
12	here.	13:14:03
13	BY MR. LIU:	13:14:07
14	Q. So that would include team members and	13:14:07
15	participants from both IVAX and Serono,	13:14:09
16	correct?	13:14:12
17	A. Yes. And if I read this correctly, they --	13:14:12
18	the way it's written is that [REDACTED]	13:14:19
19	[REDACTED]	13:14:24
20	[REDACTED]	13:14:28
21	[REDACTED]	13:14:32
22	[REDACTED]	13:14:34

1 [REDACTED] So the rest of 13:14:37
2 the team is Serono, other than IVAX. So it 13:14:40
3 is really Serono's level of confidence in us. 13:14:44
4 Q. So when it says, "The team was interested," 13:14:50
5 it's -- you believe it's referring to Serono 13:14:53
6 specifically? 13:14:57
7 A. Yes, because when one reads the sentence, it 13:14:58
8 says, "The team was interested [REDACTED] 13:15:02
9 [REDACTED] 13:15:04
10 [REDACTED] So there are only two groups of 13:15:06
11 people here, IVAX and Serono, so it -- you 13:15:09
12 know, [REDACTED] 13:15:14
13 [REDACTED] 13:15:16
14 [REDACTED] 13:15:19
15 [REDACTED] 13:15:25
16 Q. So when it states, "The team was 13:15:33
17 interested" -- actually, strike that. 13:15:35
18 Now, it states here [REDACTED] 13:15:56
19 [REDACTED] 13:16:01
20 [REDACTED] 13:16:03
21 [REDACTED] 13:16:06
22 A. Yes. 13:16:09

1	Q. And my question for you is: [REDACTED]	13:16:09
2	[REDACTED]	13:16:12
3	[REDACTED]	13:16:15
4	[REDACTED]	13:16:19
5	[REDACTED]	13:16:23
6	MS. PHENG: Objection to form,	13:16:24
7	foundation.	13:16:25
8	THE WITNESS: Yes. But, again, I	13:16:29
9	just want to qualify this to say at this	13:16:30
10	stage, and, you know, when we look at the	13:16:33
11	minutes, basically [REDACTED]	13:16:35
12	[REDACTED]	13:16:41
13	[REDACTED]	13:16:45
14	So what is in the PCT application is	13:16:46
15	after the event, right, once that formulation	13:16:50
16	is chosen and, you know, more work has been	13:16:57
17	done on it that you file a PCT application.	13:17:00
18	So it is not both at the same time.	13:17:03
19	[REDACTED]	13:17:07
20	[REDACTED]	13:17:09
21	[REDACTED]	13:17:11
22	[REDACTED]	13:17:14

1	BY MR. LIU:	13:17:16
2	Q. [REDACTED]	13:17:16
3	[REDACTED] that you're	13:17:18
4	referring to, that is being referred to --	13:17:20
5	strike that.	13:17:24
6	[REDACTED]	13:17:24
7	[REDACTED]	13:17:26
8	[REDACTED]	13:17:28
9	[REDACTED]	13:17:32
10	[REDACTED], correct?	13:17:36
11	MS. PHENG: Objection to form,	13:17:43
12	foundation.	13:17:45
13	THE WITNESS: Yes. But let me,	13:17:45
14	again, qualify that. So when you say,	13:17:46
15	[REDACTED]	13:17:49
16	[REDACTED]	13:17:50
17	[REDACTED]	13:17:52
18	[REDACTED]	13:17:55
19	And I think in general terms, yes, I	13:17:56
20	agree with what you just said. But in terms	13:18:01
21	of specifics, you know, things may have	13:18:03
22	changed after this meeting in terms of what	13:18:06

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1	was actually filed in the PCT.	13:18:08
2	BY MR. LIU:	13:18:26
3	Q. Okay. So after the two sentences that I just	13:18:37
4	read, it says, [REDACTED]	13:18:39
5	[REDACTED] and then there's a	13:18:43
6	redacted portion, and then it says, [REDACTED]	13:18:47
7	[REDACTED]	13:18:51
8	[REDACTED]	13:18:54
9	Do you see that?	13:18:56
10	A. Yes.	13:18:56
11	Q. Do you know what's redacted as the first of	13:18:57
12	these four factors?	13:19:00
13	MS. PHENG: Objection; calls for	13:19:02
14	privileged information. I am going to	13:19:03
15	instruct you not to answer.	13:19:05
16	BY MR. LIU:	13:19:07
17	Q. I'm just asking if you know what it is. You	13:19:07
18	don't have to tell me what it is.	13:19:09
19	MS. PHENG: Limiting to whether	13:19:11
20	you know, you can answer that yes or no.	13:19:12
21	THE WITNESS: I think I probably	13:19:18
22	know.	13:19:19

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1	BY MR. LIU:	13:19:19
2	Q. Do you know --	13:19:21
3	MS. PHENG: And I'm cautioning you	13:19:21
4	not to reveal the content of privileged	13:19:22
5	information or reveal the substance of any	13:19:24
6	communication with counsel.	13:19:28
7	THE WITNESS: Right. I have to	13:19:29
8	take my counsel's advice. And if it's a	13:19:32
9	redacted copy, then I should not be filling	13:19:35
10	in the blanks. And so I probably can guess	13:19:37
11	what that portion is, but I'm not at liberty	13:19:41
12	to say what it is.	13:19:44
13	BY MR. LIU:	13:19:50
14	Q. Okay. Let's take a look at the other three	13:19:50
15	factors that's listed besides the one that's	13:19:53
16	redacted.	13:19:55
17	A. Right.	13:19:56
18	Q. There's one at the end, it says, [REDACTED]	13:19:56
19	[REDACTED]	13:20:00
20	Do you see that?	13:20:00
21	A. Yes.	13:20:01
22	Q. [REDACTED]	13:20:01

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1	A. [REDACTED]	13:20:04
2	Q. [REDACTED] a factor to	13:20:09
3	consider?	13:20:13
4	A. So often when you develop something, you have	13:20:15
5	a target in mind. And, you know, in this	13:20:19
6	particular case, certainly that was very	13:20:25
7	important, because, you know, they're two	13:20:28
8	organizations who are working on the same	13:20:32
9	project, so both have to agree what the	13:20:36
10	target is.	13:20:38
11	So, you know, [REDACTED]	13:20:38
12	[REDACTED]	13:20:41
13	[REDACTED] And so if you are	13:20:45
14	not able to meet that, then, you know, we	13:20:51
15	would not proceed further or we would keep	13:20:53
16	working on it until we hit the target.	13:20:55
17	So it's important. And it's	13:21:00
18	important because it's been arrived at by	13:21:02
19	determining, you know, what would be best for	13:21:05
20	the product, for the patient, to get	13:21:07
21	regulatory approval, et cetera.	13:21:11
22	Q. So what was the [REDACTED]	13:21:15

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1 A. I don't have it at this moment in time. I --

13:21:18

2 you know, I wouldn't be able to tell.

13:21:22

3 Usually it's -- depending on organizations,

13:21:25

4 it could be quite a lengthy document.

13:21:27

5 MS. PHENG: I didn't want to

13:21:29

6 interrupt that, but I just wanted to make

13:21:31

7 clear, I object to the question in terms of

13:21:34

8 scope, relevance.

13:21:36

9 BY MR. LIU:

13:21:42

10 Q. And if we look at the third factor, it

13:21:42

11 states, [REDACTED]

13:21:47

12 Do you see that?

13:21:52

13 A. Yes.

13:21:52

14 Q. [REDACTED]

13:21:53

15 MS. PHENG: Same objection, scope,

13:21:55

16 relevance.

13:21:57

17 THE WITNESS: Yeah, [REDACTED]

13:21:59

18 [REDACTED] is that if you had, let's say,

13:22:01

19 two formulations, and you gave those two

13:22:03

20 formulations -- and as an example, let's say

13:22:07

21 we gave two formulations to -- let's pick a

13:22:10

22 number, to let's say six dogs. The first

13:22:16

1 formulation gives us a bioavailability of 13:22:21
2 50 percent, but the range of 13:22:24
3 bioavailability -- and the 50 percent less is 13:22:29
4 a mean, the range goes from 20 to, let's say, 13:22:31
5 60 percent. 13:22:36

6 The second formulation in the same 13:22:38
7 six dogs, the bioavailability is 50 percent, 13:22:41
8 but the range is, let's say, 40 -- 45 to 55. 13:22:44

9 [REDACTED] 13:22:50

10 [REDACTED] 13:22:52

11 [REDACTED] 13:22:55

12 [REDACTED] 13:22:58

13 [REDACTED] 13:23:01

14 [REDACTED] 13:23:03

15 [REDACTED] 13:23:06

16 [REDACTED] 13:23:09

17 [REDACTED] 13:23:12

18 [REDACTED] 13:23:16

19 [REDACTED] 13:23:18

20 [REDACTED] 13:23:25

21 MS. PHENG: Objection to scope, 13:23:30
22 relevance, foundation, form. 13:23:31

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1	THE WITNESS: [REDACTED]	13:23:36
2	[REDACTED]	13:23:37
3	BY MR. LIU:	13:23:50
4	Q. Dr. Dandiker, why were these four factors	13:23:50
5	being considered?	13:23:53
6	MS. PHENG: Objection; scope,	13:23:53
7	relevance, foundation.	13:23:56
8	THE WITNESS: Well, the factors	13:23:58
9	are important, because how do you determine	13:24:00
10	when you hit the target, right? So you have	13:24:03
11	to have some parameters to start with.	13:24:07
12	And, again, you know, to reiterate	13:24:10
13	that, when there are two organizations	13:24:15
14	working together, people may have different	13:24:17
15	philosophies, may have different ways of	13:24:20
16	doing things. Organizations are different.	13:24:22
17	You have to have some commonality as	13:24:26
18	to what you want to achieve together, so you	13:24:29
19	have to have -- say, Look, these are the most	13:24:33
20	important factors for this product, these are	13:24:38
21	the ones, you know, we really need to hit.	13:24:40
22	And when you do that, it focuses	13:24:41

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1 people's minds to achieve those targets so 13:24:43
2 that, you know, collectively we can move 13:24:46
3 forward. 13:24:49

4 So, you know, with most projects you 13:24:51
5 have -- you do have targets, and usually 13:24:53
6 targets are different for each one. But, you 13:24:59
7 know, in this case, I mean, these are all 13:25:02
8 reasonable targets. 13:25:06

9 BY MR. LIU: 13:25:13

10 Q. And how did these four factors contribute to 13:25:13

11 [REDACTED] 13:25:16

12 MS. PHENG: Objection; scope, 13:25:20
13 relevance, foundation. 13:25:21

14 THE WITNESS: Well, let me maybe 13:25:26
15 speak a little bit to the three which are -- 13:25:28
16 you know, which are there and not the one 13:25:35
17 which is redacted. 13:25:38

18 [REDACTED] 13:25:39

19 [REDACTED] 13:25:42

20 [REDACTED] 13:25:46

21 [REDACTED] you know, was 13:25:48

22 actually reasonably good, I believe. The 13:25:53

1	[REDACTED]	13:25:57
2	[REDACTED] which is pretty	13:25:59
3	good.	13:26:02
4	[REDACTED]	13:26:02
5	[REDACTED]	13:26:06
6	[REDACTED]	13:26:08
7	[REDACTED]	13:26:11
8	[REDACTED] So, again, that's another take.	13:26:15
9	[REDACTED]	13:26:19
10	[REDACTED]	13:26:21
11	[REDACTED]	13:26:26
12	And I don't have that in front of me, so I	13:26:29
13	wouldn't be able to tell you what. But when	13:26:31
14	it says it meets [REDACTED], it	13:26:35
15	must have met those criteria.	13:26:37
16	So, for example, a [REDACTED]	13:26:40
17	[REDACTED] could be as simple as, you know, just	13:26:44
18	one factor could be for this group of	13:26:47
19	patients a tablet size should be no bigger	13:26:49
20	than this, because they have difficulty	13:26:51
21	swallowing.	13:26:55
22	So it could be one factor and that's	13:26:58

1 what you have to meet, otherwise, you know, 13:27:01
2 it may work. But if a patient can't swallow 13:27:02
3 a tablet, it's not much good. So, you know, 13:27:05
4 that's an example. But there could be many 13:27:08
5 other things on [REDACTED] 13:27:10
6 BY MR. LIU: 13:27:29
7 Q. You stated in your answer that in terms of 13:27:30
8 [REDACTED] when you looked at the -- when 13:27:32
9 the different formulations were compared, 13:27:35
10 [REDACTED] 13:27:38
11 [REDACTED] 13:27:41
12 When you say, "Different 13:27:42
13 formulations," what did you mean there? 13:27:43
14 A. Also, I just want to kind of reiterate that I 13:27:46
15 am here, you know, and look at the minutes 13:27:50
16 and speaking on the behalf of Steve Marcus 13:27:53
17 who did this presentation, right? So this 13:27:57
18 is, I would say, secondhand. 13:28:00
19 [REDACTED] 13:28:06
20 [REDACTED] 13:28:07
21 [REDACTED] And, 13:28:10
22 you know, this is what Steve Marcus is 13:28:18

1	talking about. So these are not my words	13:28:20
2	which are documented here.	13:28:23
3	Q. No, I completely understand that. I was just	13:28:32
4	trying to understand what you meant when you	13:28:35
5	said, "Different formulations."	13:28:38
6	A. Yeah, so -- well, for instance --	13:28:39
7	MS. PHENG: Objection to form.	13:28:40
8	THE WITNESS: When we looked at	13:28:44
9	the formulations for cladribine, [REDACTED]	13:28:46
10	[REDACTED]	13:28:53
11	[REDACTED]	13:28:55
12	I mean, to start with the	13:28:58
13	cyclodextrin formulation, the reason why we	13:29:00
14	are looking at cyclodextrin were really two	13:29:02
15	or three factors. The first one was that	13:29:05
16	cyclodextrin enables you to solubilize the	13:29:09
17	drug.	13:29:13
18	Secondly -- and the more solubility	13:29:15
19	you have, you have a higher bioavailability.	13:29:18
20	Secondly, cyclodextrin was also protective in	13:29:21
21	terms of stability of the drug.	13:29:25
22	Now, cladribine itself is very acid	13:29:27

1 labile, so as soon as it hits the stomach, it 13:29:34
2 starts degrading. And if it degrades, then 13:29:37
3 it won't be effective. And not only that, 13:29:40
4 the degradation may cause other adverse 13:29:44
5 events. 13:29:48

6 So you want a product which is 13:29:48
7 bioavailable, which is stable, and that is 13:29:51
8 what the cyclodextrin allowed us to do, which 13:29:53
9 is a good thing. 13:29:56

10 The other thing about this particular 13:29:57
11 formulation, which is not mentioned here, but 13:29:59
12 it is in the PCT, is that it is amorphous. 13:30:01

13 So generally speaking, chemicals and 13:30:07
14 drugs, their preferred state is a crystalline 13:30:13
15 state. That is when they are most stable. 13:30:18

16 When you go to disordered state, 13:30:22
17 which is what amorphous is, you know, they 13:30:25
18 tend to revert back to their preferred state. 13:30:29

19 But the reason you make things 13:30:31
20 amorphous is to, again, increase 13:30:33
21 bioavailability. And the way we did this is 13:30:36
22 to lyophilize the formulation. So, 13:30:42

1 basically, freeze-dried. And so that is how
2 the cyclodextrin formulation was arrived at.

3 But to just go back to your question
4 what are the formulations, so there were
5 others. So there was one which was a
6 mucoadhesive formulation, which is a buccal
7 formulation where you took the tablet and it
8 would stick to your -- inside of your cheek
9 and the drug would release that way, or it
10 would stick in the inside of your GI tract
11 into your stomach and the drug would release
12 that way. So that was mucoadhesive tablet.

13 And when we are looking at
14 cladribine, the preference was to, you know,
15 see if we could release it in the stomach
16 using that type of mechanism. [REDACTED]

17 [REDACTED]
18 [REDACTED]

19 There were other formulations. For
20 example, there was a hard gelatin capsule
21 where the formulation was made such that when
22 the capsule dissolved, it would form an

13:30:44
13:30:46
13:30:49
13:30:51
13:30:54
13:31:00
13:31:03
13:31:06
13:31:09
13:31:13
13:31:15
13:31:18
13:31:24
13:31:25
13:31:27
13:31:30
13:31:33
13:31:36
13:31:40
13:31:42
13:31:47
13:31:50

1	emulsion.	13:31:54
2	And the idea there was the drug would	13:31:55
3	stay in the inner part of the emulsion and	13:31:58
4	that in itself would protect it in terms of	13:32:00
5	stability, but also that, you know, you get	13:32:02
6	good absorption.	13:32:08
7	And then there was another	13:32:11
8	formulation which is, again, similar concept,	13:32:12
9	but different excipients, which was a soft	13:32:15
10	gelatin capsule. So, again, the capsule	13:32:18
11	would dissolve and the contents would again	13:32:22
12	form a different type of emulsion. I believe	13:32:26
13	that was kind of high in triglyceride, so it	13:32:30
14	would, you know, act differently.	13:32:30
15	And then there were others which were	13:32:33
16	not even progressed. So we made, you know, a	13:32:35
17	dry powder emulsion, and so on and so forth.	13:32:38
18	[REDACTED]	13:32:42
19	[REDACTED]	13:32:45
20	[REDACTED]	13:32:51
21	[REDACTED]	13:32:51
22	THE COURT REPORTER: I'm sorry --	13:32:51

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1	[REDACTED]	13:32:51
2	[REDACTED]	13:32:56
3	[REDACTED]	13:32:59
4	[REDACTED]	13:33:03
5	[REDACTED]	13:33:06
6	[REDACTED] so let's	13:33:11
7	go with it. And that's how it was	13:33:16
8	determined.	13:33:18
9	BY MR. LIU:	13:33:24
10	Q. [REDACTED]	13:33:24
11	[REDACTED]	13:33:27
12	[REDACTED]	13:33:31
13	MS. PHENG: Objection to form,	13:33:32
14	foundation, scope, relevance.	13:33:34
15	THE WITNESS: I don't quite fully	13:33:42
16	understand your question. But, certainly, I	13:33:46
17	mean, if you met the four factors, then, you	13:33:47
18	know, we would have a high level of	13:33:49
19	confidence that this is going to work.	13:33:50
20	BY MR. LIU:	13:33:57
21	Q. And is your -- and [REDACTED]	13:33:57
22	[REDACTED]	13:34:01

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1	MS. PHENG: Objection --	13:34:02
2	BY MR. LIU:	13:34:03
3	Q. [REDACTED]	13:34:03
4	[REDACTED]	13:34:05
5	MS. PHENG: Objection to form,	13:34:06
6	foundation, scope, relevance.	13:34:07
7	THE WITNESS: Yes.	13:34:10
8	BY MR. LIU:	13:34:17
9	Q. And when it says, [REDACTED]	13:34:18
10	[REDACTED]	13:34:20
11	[REDACTED], correct?	13:34:24
12	A. Yes. As I mentioned earlier that, you know,	13:34:26
13	one can use that as a general term. The	13:34:34
14	specifics may have changed when the PCT was	13:34:39
15	filed.	13:34:42
16	Q. Dr. Dandiker --	13:34:44
17	MR. LIU: Actually, Rachel, can we	13:34:47
18	please move to page 3 of this -- of	13:34:49
19	Exhibit 2050.	13:34:52
20	THE TECHNICIAN: (Complies.)	13:34:53
21	MR. LIU: Actually, I apologize,	13:35:00
22	can we go back to page 2.	13:35:01

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1	THE TECHNICIAN: (Complies.)	13:35:03
2	BY MR. LIU:	13:35:13
3	Q. Do you recall any specific changes to the	13:35:13
4	formulation for the complex	13:35:19
5	cladribine-cyclodextrin complex after	13:35:24
6	August 2003 and before the Bodor PCT was	13:35:27
7	filed in March of 2004?	13:35:32
8	A. Well, I mean, one thing which I recall we	13:35:38
9	were working on at the time, was what the	13:35:42
10	ratio of cladribine to drugs should be. And	13:35:44
11	that I think may have been finalized after	13:35:51
12	these minutes, although, you know, we could	13:35:54
13	have been working on it at the time. But,	13:35:56
14	you know, in terms of data, we probably did	13:35:59
15	not have enough data, otherwise we may have	13:36:02
16	presented it at this meeting. But we did	13:36:06
17	not.	13:36:08
18	Q. So what was the ratio of cladribine to drug	13:36:11
19	in August 2003?	13:36:20
20	MS. PHENG: Objection to form,	13:36:22
21	relevance, scope.	13:36:24
22	THE WITNESS: Yeah, so again, to	13:36:28

1 clarify, it was ratio for cladribine to 13:36:30
2 cyclodextrin. So, you know, the ratio we in 13:36:33
3 the end ended up for the PCT, I believe was 1 13:36:40
4 to 1.6, so 1 of cladribine to 1.6 of 13:36:45
5 cyclodextrin. 13:36:51

6 What that actually means is that once 13:36:54
7 you go over that, so for example, if you're 13:36:57
8 more drug than that, then it would not sit 13:37:02
9 within the cyclodextrin, let's say, rig. I 13:37:06
10 mean, cyclodextrin when you put it together, 13:37:12
11 is like a cylinder. So when you kind of put 13:37:14
12 more drug, there wouldn't be enough to fit it 13:37:19
13 in. 13:37:22

14 And if there isn't enough to fit it 13:37:22
15 in, then, you know, your properties will 13:37:25
16 change and your solubility may change, your 13:37:27
17 stability may change, et cetera. So there is 13:37:33
18 an optimum. And that optimum was, you 13:37:36
19 know -- or that ratio was 1 to 1.6. 13:37:38

20 BY MR. LIU: 13:37:49

21 Q. Thank you. 13:37:49

22 So you stated that the ratio of 13:37:49

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1	cladribine to cyclodextrin was 1 to 1.6 in	13:37:51
2	the PCT. My question was different.	13:37:57
3	My question was: What was the ratio	13:37:59
4	of cladribine to cyclodextrin in August of	13:38:01
5	2003?	13:38:05
6	MS. PHENG: Objection to form,	13:38:08
7	relevance, scope.	13:38:09
8	THE WITNESS: I don't know. But,	13:38:15
9	you know, if I were to guess I would say	13:38:16
10	1 to 1.	13:38:18
11	BY MR. LIU:	13:38:22
12	Q. And what is the basis for your assumption	13:38:22
13	that it was 1 to 1 in August 2003?	13:38:25
14	MS. PHENG: Objection to scope,	13:38:30
15	relevance.	13:38:31
16	THE WITNESS: Well, we would have	13:38:32
17	just said, Look, let's go for 1 to 1 and then	13:38:33
18	work on it and really determine the	13:38:37
19	specifics. And in the PCT, you know, we did	13:38:39
20	do some work, and there is a graph, actually,	13:38:44
21	which shows, you know, how much drug to	13:38:47
22	cyclodextrin you need. So, you know, that	13:38:50

1	specificity was -- would then be arrived at.	13:38:54
2	But prior to that you say, Okay, I think, you	13:38:58
3	know, this is going to be 1 to 1, and if you	13:39:00
4	took that guess, we wouldn't -- we would not	13:39:03
5	have been far off.	13:39:05
6	BY MR. LIU:	13:39:07
7	Q. And what other ratios did you recall	13:39:07
8	developing at IVAX?	13:39:09
9	A. You know, so in the PCT we --	13:39:13
10	MS. PHENG: Objection --	13:39:16
11	THE WITNESS: Sorry.	13:39:16
12	MS. PHENG: -- scope, relevance,	13:39:17
13	form.	13:39:18
14	THE WITNESS: So in the PCT we	13:39:18
15	actually have a graph which goes through, you	13:39:20
16	know, all the cyclodextrin-cladribine	13:39:26
17	combinations we evaluated. And so that graph	13:39:31
18	shows, you know, that if you go outside that,	13:39:36
19	you would fall outside that inclusion	13:39:40
20	complex.	13:39:44
21	And so it's not that you say to	13:39:44
22	yourself, yeah, you know, I looked at, let's	13:39:50

1	say, a ratio of 2 to 1 and that did not work.	13:39:52
2	And we may have done that, but the objective	13:39:56
3	was not to see whether that didn't work. The	13:39:59
4	objective was to see what actually worked.	13:40:01
5	So that's where, you know, developing the	13:40:05
6	ratio becomes important.	13:40:07
7	And where it becomes important is	13:40:09
8	that, let us say that you had a dose of	13:40:11
9	cladribine which was 3 milligrams, then you	13:40:16
10	know how much cyclodextrin to use. If you	13:40:18
11	had a dose of cladribine which is	13:40:22
12	10 milligrams, then you'd know how much	13:40:24
13	cyclodextrin to use. So it's important to	13:40:27
14	determine that.	13:40:28
15	BY MR. LIU:	13:40:29
16	Q. Okay. Let's go on to page 3 of Exhibit 2050.	13:40:50
17	Dr. Dandiker, do you see below the heading,	13:40:59
18	Formulation Progress in Patent Issues --	13:41:03
19	A. Yes.	13:41:04
20	Q. -- that there's a Microsoft Word document	13:41:04
21	icon?	13:41:07
22	Do you see that?	13:41:07

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1	A. Yeah. Is it possible just to expand this	13:41:08
2	document a little bit?	13:41:11
3	Q. Sure.	13:41:11
4	MR. LIU: Rachel, can you just	13:41:23
5	expand a little bit?	13:41:25
6	THE TECHNICIAN: (Complies.)	13:41:26
7	THE WITNESS: Yup.	13:41:27
8	MS. PHENG: Tyler, do you think we	13:41:28
9	could take a break after you're done with	13:41:30
10	this document, assuming that you don't have a	13:41:31
11	lot more questions to go on it?	13:41:34
12	MR. LIU: I just have a couple of	13:41:36
13	questions and then we can break.	13:41:37
14	MS. PHENG: That sounds great.	13:41:40
15	Thanks.	13:41:43
16	MR. LIU: Yup.	13:41:43
17	BY MR. LIU:	13:41:43
18	Q. Dr. Dandiker, do you see that Microsoft Word	13:41:44
19	document icon?	13:41:46
20	Do you see that?	13:41:47
21	A. I do see it, yes.	13:41:47
22	Q. Do you see that it's named,	13:41:50

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1	ydandiker_amsterdam?	13:41:54
2	A. Yes.	13:41:54
3	Q. Are those your notes from attending the	13:41:54
4	August 2003 meeting?	13:41:56
5	A. I think they may be my set of slides for that	13:41:58
6	meeting.	13:42:01
7	Q. Do you know where this slide deck is stored?	13:42:09
8	A. I don't. I -- you know, when I left IVAX, I	13:42:12
9	did not take anything with me, so it must be	13:42:19
10	somewhere in IVAX archives.	13:42:23
11	Q. And when was last time you saw that slide	13:42:25
12	deck?	13:42:28
13	A. It was, you know, at the meeting.	13:42:29
14	Q. So did you share this slide deck with Serono?	13:42:33
15	A. Well, my assumption is that I must have sent	13:42:39
16	them the slide deck so it could be used at	13:42:42
17	the meeting, hence, it is there. It is named	13:42:44
18	as such, as all the other presentations which	13:42:48
19	are, you know, a person's name, underscore,	13:42:52
20	Amsterdam. So other people must have sent	13:42:54
21	their slides as well for the meeting.	13:42:57
22	Q. Do you recall what was on that slide deck?	13:43:00

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1	A. I don't. I don't. But I -- you know, as a	13:43:02
2	guess, one has to go by the minutes, right?	13:43:07
3	The minutes is a summary of what was	13:43:10
4	presented.	13:43:12
5	MR. LIU: Okay. We can take a	13:43:15
6	break.	13:43:17
7	THE VIDEOGRAPHER: Okay. We are	13:43:18
8	going off the record. The time is 1:43.	13:43:19
9	(Recess.)	13:43:22
10	THE VIDEOGRAPHER: We are back on	13:56:25
11	the record. The time is 1:56.	13:56:26
12	BY MR. LIU:	13:56:29
13	Q. Welcome back, Dr. Dandiker.	13:56:30
14	A. Hi. Yup. Thank you.	13:56:32
15	Q. Dr. Dandiker, did you discuss the substance	13:56:33
16	of your testimony with counsel during your	13:56:35
17	break?	13:56:38
18	A. No.	13:56:38
19	Q. Okay.	13:56:39
20	MR. LIU: Now, if we could bring	13:56:40
21	back up Exhibit 2050, Rachel.	13:56:41
22	THE TECHNICIAN: (Complies.)	13:56:47

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1	MR. LIU: Okay. If we could go to	13:56:49
2	page 4 of the document.	13:56:50
3	THE TECHNICIAN: (Complies.)	13:56:55
4	BY MR. LIU:	13:56:59
5	Q. Okay. Now, Dr. Dandiker, on page 4 of	13:56:59
6	Exhibit 2050, [REDACTED]	13:57:02
7	[REDACTED]	13:57:07
8	[REDACTED]	13:57:10
9	[REDACTED]	13:57:12
10	[REDACTED]	13:57:15
11	[REDACTED] and, "It was agreed that	13:57:18
12	Yogesh would make a 10-milligram tablet, in	13:57:21
13	addition to the 3 milligram tablet already	13:57:24
14	proposed."	13:57:28
15	Do you see that?	13:57:28
16	A. Yup.	13:57:29
17	MS. PHENG: Objection to scope,	13:57:30
18	relevance.	13:57:31
19	BY MR. LIU:	13:57:36
20	Q. Dr. Dandiker, so at this point in two	13:57:36
21	thousand -- in August of 2003, you had	13:57:39
22	already made the 3 milligram tablet; is that	13:57:42

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1	correct?	13:57:45
2	A. Yes. It looks like it, yes.	13:57:45
3	MS. PHENG: Same objection.	13:57:47
4	BY MR. LIU:	13:57:51
5	Q. And then this document states that it was	13:57:51
6	proposed that you make the 10-milligram	13:57:56
7	tablet, correct?	13:57:58
8	MS. PHENG: Same objection.	13:57:59
9	THE WITNESS: Yes.	13:58:00
10	BY MR. LIU:	13:58:00
11	Q. Okay. What was the process for making the	13:58:02
12	10-milligram tablet from the 3-milligram	13:58:05
13	tablet?	13:58:12
14	MS. PHENG: Same objection.	13:58:12
15	THE WITNESS: The process would	13:58:13
16	have been essentially the same, it's just	13:58:14
17	that the quantities would change. So the	13:58:18
18	process would be the same. The one -- that	13:58:22
19	is why, as we were discussing earlier in	13:58:29
20	terms of ratios of cladribine to	13:58:31
21	cyclodextrin, once you know that, you know,	13:58:34
22	you can scale it up. So the process	13:58:36

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1	essentially would have been the same.	13:58:40
2	BY MR. LIU:	13:58:44
3	Q. So would it have been difficult to scale up	13:58:44
4	from the 3-milligram tablet to the	13:58:46
5	10-milligram tablet?	13:58:48
6	MS. PHENG: Same objection.	13:58:50
7	THE WITNESS: Not really. The	13:58:51
8	unknown, of course, is stability. So unless	13:58:55
9	you put something on stability, you don't	13:58:59
10	know whether going from 3 milligram to	13:59:04
11	10 milligrams, you know, your stability is	13:59:08
12	going to be the same. Theoretically, it	13:59:10
13	should be the same. But, you know, you	13:59:13
14	always get surprises.	13:59:15
15	BY MR. LIU:	13:59:19
16	Q. Now, below that text there's a table with	13:59:20
17	action points.	13:59:24
18	Do you see that?	13:59:25
19	A. Yup. Yup.	13:59:25
20	Q. Okay. And if you look at the fourth row down	13:59:26
21	from this table, there's a row with	13:59:32
22	G. Francis and M. Lopez-Bresnahan.	13:59:35

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1	Do you see that?	13:59:44
2	A. Yes.	13:59:44
3	Q. And, of course, as we talked about earlier,	13:59:45
4	that refers to Gordon Francis and	13:59:47
5	Maria Lopez-Bresnahan, correct?	13:59:50
6	A. Yes.	13:59:54
7	Q. Okay. And do you see that this action point	13:59:54
8	states that, "G. Francis to facilitate	13:59:56
9	contact between IVAX and J.P. deLuca"?	13:59:59
10	Do you see that?	14:00:02
11	A. Yes, I do.	14:00:02
12	Q. And who is J.P. deLuca?	14:00:03
13	A. I don't know. But just reading this now, it	14:00:06
14	feels like, you know, that must be somebody	14:00:15
15	who is not from IVAX. It could be, you know,	14:00:18
16	Serono or somebody from outside.	14:00:24
17	Q. Could J.P. deLuca be referring to the	14:00:31
18	Gianpiero deLuca that I was referring to	14:00:33
19	earlier in your deposition today?	14:00:36
20	A. I assume so. But, you know, certainly, the	14:00:38
21	way their sentence reads is contact between	14:00:42
22	IVAX and J.P. deLuca, so J.P. deLuca is	14:00:47

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1	not -- you know, not part of IVAX.	14:00:50
2	Q. Who at IVAX was Gordon Francis tasked with	14:00:55
3	facilitating contact?	14:00:59
4	MS. PHENG: Objection to form,	14:01:02
5	foundation.	14:01:03
6	THE WITNESS: I can't really	14:01:03
7	comment on that. I don't know.	14:01:04
8	BY MR. LIU:	14:01:07
9	Q. Okay. If we go to the last row of the action	14:01:08
10	point table.	14:01:11
11	A. Yeah.	14:01:12
12	Q. Do you see that you have an action point for	14:01:12
13	yourself, correct?	14:01:14
14	A. Yes.	14:01:15
15	Q. And your action item states, "Forward	14:01:17
16	formulation and analytical development	14:01:19
17	reports, stability data, and the patents	14:01:22
18	filed on the oral cladribine formulation."	14:01:25
19	Do you see that?	14:01:31
20	A. I do see that, yes.	14:01:31
21	Q. What formulation and analytical development	14:01:32
22	reports is this referring to?	14:01:35

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1	A. So this must be referring to the 3-milligram	14:01:37
2	tablet, because the 10-milligram at this time	14:01:39
3	was not made.	14:01:43
4	Q. And did you cite to these formulation and	14:01:48
5	analytical development reports in your	14:01:52
6	declaration that you submitted in this	14:01:55
7	proceeding?	14:01:56
8	MS. PHENG: Objection to form,	14:01:57
9	scope, relevance.	14:01:59
10	THE WITNESS: Sorry, can you	14:02:05
11	repeat the question again?	14:02:07
12	BY MR. LIU:	14:02:08
13	Q. Sure. Did you cite to these formulation and	14:02:09
14	analytical development reports in the	14:02:11
15	declaration that you submitted in this	14:02:13
16	proceeding?	14:02:14
17	MS. PHENG: Same objections.	14:02:15
18	THE WITNESS: No, I did not cite	14:02:16
19	the formulation and analytical reports in the	14:02:20
20	declaration.	14:02:22
21	BY MR. LIU:	14:02:24
22	Q. And when was the last time you saw these	14:02:24

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1	reports?	14:02:26
2	A. It must be when I was at IVAX, so two	14:02:31
3	thousand -- before 2004.	14:02:34
4	Q. Okay. And it also states, "Stability data."	14:02:39
5	Do you see that?	14:02:43
6	A. Yup.	14:02:44
7	Q. And are you -- is it your recollection that	14:02:44
8	the stability data is also referring to the	14:02:47
9	3-milligram tablet?	14:02:49
10	A. Yes, because what these minutes show is that	14:02:51
11	the 10-milligram tablet at this moment in	14:02:56
12	time had not been made.	14:02:58
13	Q. Do you recall if you actually forwarded these	14:03:03
14	documents?	14:03:05
15	A. Sorry, can you please say that again?	14:03:09
16	Q. Do you recall actually forwarding these	14:03:11
17	reports and data?	14:03:14
18	A. I don't recall forwarding them. But the way	14:03:18
19	I work, I usually follow up on my actions, so	14:03:22
20	I must have.	14:03:25
21	Q. And I'm assuming your task is to forward	14:03:26
22	these reports and data to Serono, correct?	14:03:29

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1	A. Yes.	14:03:32
2	Q. Okay. And do you see the last item, it says,	14:03:36
3	"Patents filed on the oral cladribine	14:03:38
4	formulations"?	14:03:43
5	Do you see that?	14:03:43
6	A. Yes.	14:03:43
7	Q. What patents are they referring to?	14:03:44
8	MS. PHENG: I'm just going to	14:03:45
9	caution the witness not to reveal any -- the	14:03:47
10	substance of any communication with counsel	14:03:49
11	or any privileged information, but you may	14:03:51
12	answer to the extent you know.	14:03:52
13	THE WITNESS: Yeah, I -- at this	14:03:58
14	moment in time, I just actually don't know.	14:04:00
15	The only thing I can assume is that the first	14:04:03
16	PCT was filed in 2004, so it could be	14:04:07
17	referring to that.	14:04:12
18	It could also be referring to	14:04:13
19	applications which Dr. Bodor had filed even	14:04:17
20	before that. So it could be referring to	14:04:19
21	that. I don't know.	14:04:21
22	Because the other filing was after	14:04:30

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1	that, after -- you know, was quite later.	14:04:32
2	MR. LIU: If we could go to page 7	14:04:50
3	of Exhibit 2050.	14:04:52
4	THE TECHNICIAN: (Complies.)	14:04:53
5	BY MR. LIU:	14:04:55
6	Q. Dr. Dandiker, do you see on this page a list	14:04:55
7	of activities and target dates?	14:04:58
8	A. Yeah. Yes, I do.	14:05:01
9	Q. Okay. If you go further down the page, do	14:05:02
10	you see a heading titled, Phase 3 Pivotal	14:05:06
11	Study?	14:05:06
12	Do you see that?	14:05:13
13	A. Yup.	14:05:13
14	Q. Do you have an understanding of when Serono	14:05:13
15	began Phase 3 trials for oral cladribine?	14:05:17
16	A. I don't. I -- you know, these are dates, and	14:05:20
17	dates, if anything, at this stage are	14:05:28
18	targets. But when they actually started the	14:05:30
19	study, I wouldn't know. And I think as we	14:05:33
20	discussed earlier this morning, it's very	14:05:35
21	difficult actually to recruit patients for	14:05:39
22	this condition, and phase 3 enrolls a lot of	14:05:43

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1	patients. So I wouldn't know when they --	14:05:47
2	they did their recruitment and the study was	14:05:50
3	done.	14:05:53
4	Q. So you don't have an understanding of whether	14:05:53
5	any of these target dates were actually met,	14:05:55
6	correct?	14:05:58
7	A. That's right. So these --	14:05:58
8	Q. Sorry. Go ahead.	14:06:03
9	A. These are minutes in 2003. And by, you know,	14:06:04
10	2004, I had left the organization, so I do	14:06:10
11	not know what happened afterwards.	14:06:13
12	Q. Thank you.	14:06:14
13	MR. LIU: Rachel, you can take	14:06:16
14	that down.	14:06:18
15	THE TECHNICIAN: (Complies.)	14:06:19
16	MR. LIU: Can we bring back -- I	14:06:20
17	mean, can we bring up Exhibit 2049, which is	14:06:22
18	exhibit -- I mean, Tab 6.	14:06:25
19	THE TECHNICIAN: (Complies.)	14:06:28
20	BY MR. LIU:	14:06:40
21	Q. Dr. Dandiker, do you recognize this document?	14:06:41
22	A. I do.	14:06:43

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1	Q. When was the last time you saw this document?	14:06:43
2	A. I think when counsel forwarded it to me	14:06:50
3	fairly recently. This is just prior to my	14:06:55
4	declaration.	14:07:00
5	Q. And when was the last time you recall seeing	14:07:02
6	this document prior to being retained by	14:07:06
7	Merck in this proceeding?	14:07:09
8	A. I actually may have seen it when I was at	14:07:11
9	IVAX, but I don't have a clear recollection	14:07:18
10	of having seen it.	14:07:21
11	Q. So you don't have a specific recollection of	14:07:24
12	actually seeing this document --	14:07:26
13	A. No --	14:07:28
14	Q. -- at IVAX, correct?	14:07:30
15	A. Yes. So day to day, I mean, you know,	14:07:32
16	there's a lot of communication, many, many --	14:07:35
17	in a week or in a month, many hundreds of	14:07:41
18	emails. So this is just one of many.	14:07:43
19	Q. Dr. Dandiker, what was the purpose of this	14:07:45
20	document?	14:07:51
21	MS. PHENG: Objection to form,	14:07:51
22	foundation.	14:07:52

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1	THE WITNESS: Well, I think when	14:07:55
2	you look at the document, it is really, I	14:07:57
3	would say, an equivalent of a pre-R&D	14:08:02
4	submission you would do in the US, but this	14:08:07
5	is to the Swedish authorities for cladribine.	14:08:09
6	So this is, you know, if anything trying to	14:08:12
7	get the first feedback from the regulators.	14:08:15
8	MR. LIU: If we could go to PDF	14:08:26
9	page 9 of this document.	14:08:28
10	THE TECHNICIAN: (Complies.)	14:08:30
11	BY MR. LIU:	14:08:32
12	Q. Dr. Dandiker, do you see that there's a	14:08:32
13	heading called, Introduction?	14:08:34
14	Do you see that?	14:08:36
15	A. Yup, I do.	14:08:36
16	MR. LIU: And if you could scroll	14:08:42
17	down a little bit.	14:08:44
18	THE TECHNICIAN: (Complies.)	14:08:45
19	BY MR. LIU:	14:08:47
20	Q. If you see five paragraphs down, it says,	14:08:47
21	"Serono partnered with IVAX Research,	14:08:51
22	Incorporated, (IVAX), in 2002, to develop an	14:08:55

1	oral formulation of cladribine for the	14:08:58
2	treatment of MS."	14:09:03
3	Do you see that?	14:09:04
4	And then it says, "Two clinical	14:09:05
5	studies to study the pharmacokinetics and	14:09:06
6	bioavailability of three tablet and capsule	14:09:10
7	oral formulations of cladribine are currently	14:09:13
8	being conducted in MS patients."	14:09:14
9	Do you see that?	14:09:16
10	A. Yes.	14:09:16
11	Q. Is one of the oral formulations of cladribine	14:09:27
12	that was being conducted in MS patients the	14:09:30
13	complex cladribine-cyclodextrin complex	14:09:34
14	formulation?	14:09:36
15	A. Yes.	14:09:37
16	MS. PHENG: Objection to	14:09:37
17	foundation.	14:09:38
18	THE WITNESS: Yes, I believe so.	14:09:38
19	MR. LIU: If you'd go to page 18.	14:09:54
20	THE TECHNICIAN: (Complies.)	14:09:57
21	BY MR. LIU:	14:09:58
22	Q. And do you see the heading 2.2.4,	14:09:58

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1	Product Stability?	14:09:58
2	Do you see that?	14:10:03
3	A. Yes.	14:10:04
4	Q. Now, under the heading, Product Stability,	14:10:04
5	the document talks about three formulations	14:10:07
6	that were being evaluated.	14:10:09
7	Do you see that?	14:10:12
8	A. Yup.	14:10:13
9	Q. And it says the three formulations are the	14:10:16
10	cyclodextrin complex tablet, mucoadhesive	14:10:21
11	tablet, and the hard gelatin capsule, right?	14:10:23
12	A. Yes.	14:10:23
13	Q. And the cyclodextrin complex tablet is -- has	14:10:24
14	the same formulation as the complex	14:10:27
15	cladribine-cyclodextrin complex, correct?	14:10:30
16	A. Yes.	14:10:32
17	MS. PHENG: Objection to form,	14:10:32
18	foundation, scope and relevance.	14:10:33
19	BY MR. LIU:	14:10:36
20	Q. Okay. And then if you go one paragraph down,	14:10:36
21	it says, [REDACTED]	14:10:42
22	[REDACTED]	14:10:44

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1	[REDACTED]	14:10:47
2	[REDACTED]	14:10:49
3	[REDACTED]	14:10:52
4	[REDACTED]	14:10:52
5	Do you see that?	14:10:57
6	A. Yup.	14:10:57
7	MS. PHENG: Same objections.	14:10:59
8	BY MR. LIU:	14:11:01
9	Q. What is actually being said here for this	14:11:04
10	sentence?	14:11:07
11	MS. PHENG: Same objections.	14:11:07
12	THE WITNESS: Sorry, repeat that	14:11:09
13	again, please.	14:11:10
14	BY MR. LIU:	14:11:11
15	Q. What is it trying to say here in this	14:11:11
16	sentence?	14:11:14
17	MS. PHENG: Same objections.	14:11:14
18	THE WITNESS: Well, I think you	14:11:15
19	have to read the whole -- you know, the whole	14:11:16
20	section on stability. So what it's really	14:11:23
21	saying is that the [REDACTED]	14:11:25
22	[REDACTED]	14:11:30

1	[REDACTED]	14:11:35
2	[REDACTED]	14:11:38
3	[REDACTED]	14:11:42
4	[REDACTED] And if it's stable for at least	14:11:46
5	three months, that's pretty good.	14:11:49
6	Generally speaking, if a tablet is	14:11:51
7	stable let's say for six months at [REDACTED]	14:11:54
8	that means that you are going to have a	14:11:59
9	product which is stable for two years.	14:12:00
10	Obviously, you know, we don't didn't have	14:12:04
11	that, you know, six months data, but we have	14:12:06
12	three months data, which looked good.	14:12:09
13	And then once one starts reading the	14:12:11
14	rest of the stability section, what it is	14:12:16
15	saying is that in terms of stability, the	14:12:18
16	cyclodextrin formulation is actually better	14:12:22
17	than the others.	14:12:24
18	MR. LIU: Okay. Let's go to	14:12:33
19	page 33.	14:12:34
20	THE TECHNICIAN: (Complies.)	14:12:35
21	BY MR. LIU:	14:12:36
22	Q. Now, do you see under the heading 4.2.3,	14:12:37

1	Ongoing Pharmacokinetic Studies?	14:12:45
2	A. Yup. Yes.	14:12:45
3	Q. And the third sentence after that heading, it	14:12:46
4	talks about, [REDACTED]	14:12:53
5	[REDACTED]	14:12:56
6	[REDACTED]	14:12:59
7	[REDACTED] --	14:13:01
8	A. Right.	14:13:02
9	Q. -- [REDACTED]	14:13:02
10	[REDACTED]	14:13:04
11	Do you see that?	14:13:05
12	A. Yes.	14:13:06
13	Q. [REDACTED]	14:13:06
14	[REDACTED]	14:13:10
15	[REDACTED]	14:13:12
16	MS. PHENG: Objection to scope,	14:13:13
17	relevance.	14:13:14
18	THE WITNESS: I think it must be	14:13:16
19	before -- before the set of minutes which we	14:13:17
20	looked at previously before the Amsterdam	14:13:22
21	meeting, because in those minutes there's a	14:13:24
22	[REDACTED], so it must have	14:13:28

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1	been done prior to that. But I would not be	14:13:33
2	able to give you an exact date, because the	14:13:36
3	person responsible for that was Dr. Marcus.	14:13:38
4	BY MR. LIU:	14:13:41
5	Q. Well, [REDACTED]	14:13:42
6	[REDACTED] -- sorry, strike that.	14:13:45
7	Were these pharmacokinetic analyses	14:13:50
8	performed prior to the signing of the joint	14:13:54
9	research agreement in October 2002?	14:13:57
10	MS. PHENG: Objection to form,	14:14:00
11	foundation, scope, relevance.	14:14:01
12	THE WITNESS: I believe not. That	14:14:05
13	is because I think the studies were done	14:14:09
14	after signing of that agreement. And, you	14:14:12
15	know, the objective of the study, and it kind	14:14:18
16	of lays out in this document, is to select	14:14:23
17	the most appropriate formulation. So the	14:14:27
18	agreement must have been signed prior to	14:14:30
19	doing the studies.	14:14:33
20	MR. LIU: Okay. You can take that	14:14:39
21	down.	14:14:41
22	THE TECHNICIAN: (Complies.)	14:14:41

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1	MR. LIU: Can we bring back up	14:14:43
2	Dr. Dandiker's declaration, which is	14:14:44
3	Exhibit 2055.	14:14:47
4	THE TECHNICIAN: (Complies.)	14:14:50
5	BY MR. LIU:	14:15:02
6	Q. Dr. Dandiker, if we can actually scroll	14:15:02
7	down --	14:15:08
8	MR. LIU: Actually, can we go to	14:15:15
9	page 3 of his CV.	14:15:16
10	THE TECHNICIAN: (Complies.)	14:15:16
11	MR. LIU: So, yes, one more page.	14:15:18
12	THE TECHNICIAN: (Complies.)	14:15:18
13	MR. LIU: Right there, yes.	14:15:19
14	BY MR. LIU:	14:15:19
15	Q. And if we go to -- scroll down in the	14:15:19
16	document, if you see under the heading, you	14:15:22
17	talk about your role at IVAX.	14:15:24
18	Do you see that?	14:15:25
19	A. Right.	14:15:26
20	Q. And if you go to the fourth bullet point, do	14:15:27
21	you see that you state that you provided,	14:15:32
22	"Significant input in patent and business	14:15:35

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1	development strategies"?	14:15:37
2	Do you see that?	14:15:37
3	A. Right.	14:15:38
4	MS. PHENG: I just want to caution	14:15:38
5	the witness, you know, please don't reveal	14:15:40
6	any privileged information, any -- the	14:15:43
7	substance of any communications with counsel.	14:15:45
8	THE WITNESS: Yup.	14:15:47
9	BY MR. LIU:	14:15:50
10	Q. Dr. Dandiker, before we get into that, what	14:15:50
11	was the process for filing a patent at IVAX?	14:15:52
12	MS. PHENG: Objection to form,	14:15:58
13	scope, relevance, foundation.	14:15:59
14	THE WITNESS: Well, let me first	14:16:03
15	actually go to why this is on the CV, and	14:16:04
16	that is --	14:16:10
17	BY MR. LIU:	14:16:11
18	Q. So can you answer my question and then we can	14:16:12
19	get back to that?	14:16:14
20	A. Sure.	14:16:14
21	Q. We'll get back that. Thank you.	14:16:14
22	A. Sorry, repeat the question again, please.	14:16:16

1 Q. Sure. What was the process for filing a
2 patent at IVAX?

3 MS. PHENG: Same objection.

4 THE WITNESS: Yeah, so the process
5 was that initially, you know, the idea would
6 be discussed amongst the scientists and then
7 there would be quite a lot of discussion with
8 patent attorneys whether it was feasible to
9 patent, but also whether it was desirable to
10 patent.

11 Because often, you know, when you
12 patent, you're also disclosing your
13 technology. And once a determination was
14 made that it is desirable to patent, there
15 would be interactions between the scientists
16 and the attorneys to really draft the patent.

17 So the drafting would actually be
18 done by the attorneys. The scientists would
19 provide the information and data. And then
20 there's a lot of back and forth, because, you
21 know, in the end you say something and
22 somebody else writes it, it may look

14:16:18
14:16:24
14:16:26
14:16:28
14:16:29
14:16:36
14:16:41
14:16:44
14:16:49
14:16:53
14:16:54
14:16:57
14:17:01
14:17:04
14:17:08
14:17:11
14:17:16
14:17:19
14:17:22
14:17:25
14:17:29
14:17:31

1	different when you read it again. So there's	14:17:33
2	a lot of back and forth.	14:17:35
3	But, in essence, that's how it was	14:17:38
4	done. So that's how, kind of, patents were	14:17:41
5	filed at IVAX.	14:17:47
6	BY MR. LIU:	14:17:50
7	Q. How big was the patent team at IVAX?	14:17:50
8	MS. PHENG: Objection to scope,	14:17:53
9	relevance.	14:17:55
10	THE WITNESS: There was no patent	14:17:56
11	team at IVAX. I mean, certainly not in the	14:17:57
12	UK. There was -- you know, I believe in IVAX	14:18:00
13	US, they may have patent attorneys in-house.	14:18:08
14	But certainly in the UK there was no patent	14:18:13
15	team. So it was we as individuals, you know,	14:18:16
16	interacted with patent attorneys to get	14:18:21
17	either patents filed or challenged or	14:18:26
18	whatever it was.	14:18:28
19	BY MR. LIU:	14:18:31
20	Q. Do you recall how many patent attorneys were	14:18:32
21	in-house in the IVAX US office?	14:18:36
22	A. No --	14:18:39

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1	MS. PHENG: Objection to scope,	14:18:40
2	relevance.	14:18:41
3	THE WITNESS: No, I don't know. I	14:18:42
4	met only one patent attorney at the IVAX US	14:18:44
5	office, and I do not know whether she was	14:18:47
6	in-house or she had just come to -- come for	14:18:53
7	that purpose that day. I don't know. I mean	14:18:58
8	she could have been in-house, but I wouldn't	14:19:01
9	be able to say for sure.	14:19:05
10	BY MR. LIU:	14:19:07
11	Q. And who was that in-house attorney?	14:19:07
12	A. I don't remember her name.	14:19:09
13	Q. Okay. But you remember she was -- it was a	14:19:11
14	female, correct?	14:19:15
15	A. Yeah, I remember she was female.	14:19:16
16	Q. Okay. Now, back to your CV where you discuss	14:19:20
17	providing significant input in patent and	14:19:26
18	business development strategies, my question	14:19:29
19	for you is what did you mean by providing	14:19:31
20	significant input in patent strategies?	14:19:34
21	MS. PHENG: Objection to	14:19:36
22	privilege. I'd caution you not to reveal the	14:19:39

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1	substance of any communications with counsel	14:19:41
2	and any privileged information. You may	14:19:43
3	answer generally without getting into the	14:19:45
4	legal issues.	14:19:47
5	BY MR. LIU:	14:19:47
6	Q. And I want to clarify, I'm not asking about	14:19:50
7	your privileged communications with counsel.	14:19:54
8	I'm just asking about what you meant here in	14:19:56
9	terms of providing significant input in	14:19:58
10	patent strategies.	14:19:59
11	A. Yeah. So --	14:20:00
12	MS. PHENG: And also just	14:20:01
13	objection to scope, relevance.	14:20:02
14	But you may answer.	14:20:04
15	THE WITNESS: Yeah, so I just want	14:20:05
16	to go back to the fact that IVAX was a	14:20:08
17	generic company. So I would say a large part	14:20:11
18	of my job was developing generic products,	14:20:16
19	and that entailed makings to patent and	14:20:21
20	business strategies. They were both	14:20:25
21	intertwined.	14:20:27
22	But it also meant that we were not	14:20:27

1 only filing certain patents for certain
2 things, but more so for the generic side, we
3 were actually challenging patents. And I
4 think it's what we are doing today, which is
5 in reverse of that. So the business strategy
6 is actually intertwined with that.

7 For example, if a particular patent
8 was expiring on a certain date, you know, we
9 were -- we would have a discussion whether we
10 would want to develop that product or not and
11 whether there were ways to get around what
12 was in the patent or not or whether we would
13 get challenged or whether we would win or not
14 and what the competition was doing.

15 So that is all part and parcel of
16 what we did every day in terms of the generic
17 side of the business, which is -- you know,
18 for IVAX, which was the bulk of their
19 business.

20 BY MR. LIU:

21 Q. And how many patents did you provide input on
22 while you were at IVAX?

14:20:32
14:20:34
14:20:41
14:20:44
14:20:47
14:20:56
14:20:58
14:20:59
14:21:01
14:21:04
14:21:08
14:21:13
14:21:16
14:21:18
14:21:20
14:21:25
14:21:27
14:21:29
14:21:32
14:21:38
14:21:39
14:21:41

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1	MS. PHENG: Objection to	14:21:43
2	relevance, scope.	14:21:43
3	THE WITNESS: For IVAX, I mean, I	14:21:44
4	think it was just one. And, you know, but	14:21:45
5	there were always -- you know, the objective	14:21:49
6	was the other way around, which is can we get	14:21:54
7	around somebody else's patent, be it, you	14:21:57
8	know, formulation or chemical compound or	14:22:02
9	could be some other aspect of it, or maybe we	14:22:06
10	can't. But certainly we would have those	14:22:08
11	kind of discussions all the time.	14:22:11
12	And there were many things which we	14:22:13
13	also discussed which could be patentable, but	14:22:14
14	we did not patent. Because as you know,	14:22:19
15	patenting itself is expensive. And if you're	14:22:21
16	not going to proceed with a project, it is no	14:22:24
17	point in patenting an idea, because it -- in	14:22:29
18	many ways, you're just giving that idea away	14:22:32
19	if you are not going to use it.	14:22:35
20	BY MR. LIU:	14:22:41
21	Q. And when you say that you provided input on	14:22:41
22	just one patent while you were at IVAX, was	14:22:43

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1	that the Bodor PCT that we reviewed earlier?	14:22:47
2	A. No, no, I mean besides the Bodor PCT. I	14:22:51
3	think there was one on Gabapentin which we	14:22:55
4	filed. I don't know what the kind of -- the	14:22:59
5	declaration here with me, I don't know	14:23:06
6	whether it's documented anywhere.	14:23:08
7	Yeah, I think the kind of first,	14:23:12
8	second, third, fourth one on the patent was,	14:23:15
9	you know, Woolfe, et cetera, is filed from	14:23:19
10	IVAX.	14:23:24
11	MR. LIU: Okay. We can take that	14:23:38
12	down.	14:23:39
13	THE TECHNICIAN: (Complies.)	14:23:40
14	MR. LIU: Rachel, can we bring	14:23:41
15	back up the Bodor PCT, which was Tab 2, and	14:23:43
16	Exhibit 1022.	14:23:47
17	THE TECHNICIAN: (Complies.)	14:23:48
18	MR. LIU: And if we could go to	14:23:55
19	PDF page 25 of the Bodor PCT.	14:23:57
20	THE TECHNICIAN: (Complies.)	14:24:04
21	BY MR. LIU:	14:24:05
22	Q. Dr. Bodor -- I mean, Dr. Dandiker, this is on	14:24:06

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1	page 23 of your Bodor PCT.	14:24:08
2	A. All right.	14:24:10
3	Q. And if we could go to line -- starting on	14:24:11
4	line 24.	14:24:15
5	A. Right.	14:24:19
6	Q. Do you see the sentence starting with, "For	14:24:20
7	further dosing information"?	14:24:23
8	Do you see that?	14:24:24
9	A. Yeah.	14:24:25
10	Q. And do you see in that sentence there are	14:24:26
11	some specific application numbers that are	14:24:29
12	left blank?	14:24:32
13	Do you see that?	14:24:33
14	A. Yup, I do.	14:24:33
15	Q. But in the brackets next to the blank space,	14:24:35
16	do you see some attorney docket numbers?	14:24:39
17	A. Yes.	14:24:43
18	Q. Do you see that?	14:24:43
19	A. Yup.	14:24:44
20	Q. Now, where it says, "IVAX," followed by some	14:24:44
21	numbers and letters, is the -- are those	14:24:48
22	numbers referring to an IVAX numbering system	14:24:52

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1	for tracking patent filings?	14:24:55
2	MS. PHENG: Objection to form,	14:24:57
3	foundation.	14:24:59
4	THE WITNESS: I assume so, because	14:25:02
5	it says, "IVAX," on there. So it must be.	14:25:04
6	BY MR. LIU:	14:25:26
7	Q. So is it your understanding that those	14:25:26
8	numbers are referring to an IVAX numbering	14:25:30
9	system for tracking patent filings?	14:25:32
10	MS. PHENG: Objection to form,	14:25:35
11	foundation.	14:25:37
12	THE WITNESS: Yeah, as I just	14:25:39
13	said, I assume so just because, you know, it	14:25:41
14	says IVAX numbers.	14:25:43
15	BY MR. LIU:	14:25:50
16	Q. Before you filed the Bodor PCT, did you	14:25:51
17	review those two applications that are being	14:25:54
18	mentioned here?	14:25:57
19	A. No.	14:25:59
20	Q. Have you ever known what their subject matter	14:26:03
21	is?	14:26:06
22	A. When I read this, and I'm reading the second	14:26:08

1	line from the bottom both entitled,	14:26:11
2	Cladribine Regimen for Treating Multiple	14:26:16
3	Sclerosis, this is not my area at all, so I	14:26:21
4	would not have reviewed them.	14:26:23
5	Q. Do you know who would know about these	14:26:25
6	applications?	14:26:26
7	A. I would not.	14:26:27
8	Q. Did you ask anyone at IVAX to see these	14:26:34
9	particular applications?	14:26:38
10	A. I -- by this, I had no business to ask. This	14:26:40
11	has nothing to do with me.	14:26:44
12	MR. LIU: Okay. We can take that	14:26:58
13	down.	14:27:00
14	THE TECHNICIAN: (Complies.)	14:27:00
15	BY MR. LIU:	14:27:06
16	Q. Dr. Dandiker, you referred to the term	14:27:06
17	"invent" or "invented" a number of times in	14:27:09
18	your declaration. And my question for you	14:27:13
19	is: Do you have an understanding of the	14:27:16
20	legal requirements of inventorship?	14:27:18
21	MS. PHENG: Objection to form,	14:27:20
22	foundation, scope, relevance.	14:27:23

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1	THE WITNESS: I believe I do.	14:27:28
2	BY MR. LIU:	14:27:32
3	Q. Okay. And what is your understanding of	14:27:33
4	those requirements?	14:27:34
5	A. Well, in the colloquial language, it is when	14:27:35
6	you have invented something which I would say	14:27:41
7	nobody else has, but also you are, you know,	14:27:43
8	let's say a prime contributor to that	14:27:48
9	invention.	14:27:51
10	So if you were to develop a	14:27:56
11	formulation, if you break it down, you say	14:27:57
12	what in this formulation did you contribute.	14:27:59
13	And, you know, that's how I understand it.	14:28:02
14	Other people may see it differently.	14:28:07
15	Q. I see that you used the word "invent" in your	14:28:10
16	definition. I just wanted to know what is	14:28:13
17	your understanding of the legal requirements	14:28:15
18	of inventorship?	14:28:18
19	MS. PHENG: Same objections.	14:28:20
20	THE WITNESS: I think I just kind	14:28:23
21	of outlined my understanding. In terms of	14:28:26
22	legal definition, I don't have a legal	14:28:28

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1	definition in front of me to read it out.	14:28:30
2	I'm sure there is a legal definition.	14:28:35
3	BY MR. LIU:	14:28:37
4	Q. But you don't have an understanding of what	14:28:38
5	the legal requirements for inventorship is,	14:28:39
6	correct?	14:28:42
7	MS. PHENG: Same objections.	14:28:42
8	THE WITNESS: Yeah. I mean, if	14:28:43
9	you want to be pedantic, yes.	14:28:49
10	BY MR. LIU:	14:28:51
11	Q. Do you have an understanding of the legal	14:28:52
12	requirements for conception?	14:28:54
13	MS. PHENG: Same objections.	14:29:00
14	THE WITNESS: For invention?	14:29:02
15	BY MR. LIU:	14:29:03
16	Q. No. Do you have an understanding of the	14:29:03
17	legal requirements for conception?	14:29:04
18	A. Conception. I --	14:29:07
19	MS. PHENG: Same objections.	14:29:08
20	THE WITNESS: Yeah, I don't. If I	14:29:09
21	had it written down in front of me, I could	14:29:13
22	read it out.	14:29:15

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1	BY MR. LIU:	14:29:17
2	Q. Do you have an understanding of the legal	14:29:18
3	requirements for reduction to practice?	14:29:19
4	MS. PHENG: Same objection.	14:29:23
5	THE WITNESS: I -- I don't.	14:29:24
6	BY MR. LIU:	14:29:28
7	Q. Do you have an understanding of the	14:29:28
8	differences between conception and	14:29:30
9	inventorship?	14:29:32
10	MS. PHENG: Same objections.	14:29:33
11	THE WITNESS: I would not.	14:29:36
12	BY MR. LIU:	14:29:46
13	Q. Did you have an understanding of the legal	14:29:46
14	requirements for inventorship when you signed	14:29:48
15	your declaration that you submitted in this	14:29:51
16	proceeding?	14:29:54
17	MS. PHENG: Same objection.	14:29:55
18	THE WITNESS: Yeah, my	14:29:57
19	understanding is that if you invented	14:29:58
20	something and if there's a patent application	14:30:01
21	assigned to your name, then, you know, you --	14:30:04
22	that's what you're signing for and this is,	14:30:08

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1	you know, what you have invented.	14:30:12
2	BY MR. LIU:	14:30:17
3	Q. I think my question was slightly different.	14:30:17
4	My question was: Did you have an	14:30:19
5	understanding of the legal requirements for	14:30:21
6	inventorship when you signed your declaration	14:30:24
7	that you submitted in this proceeding?	14:30:27
8	MS. PHENG: Same objections.	14:30:29
9	THE WITNESS: I would, in many	14:30:33
10	ways, say that if that was sent to me by my	14:30:36
11	counsel to sign, then my assumption would be	14:30:41
12	that they have that legal understanding, and	14:30:46
13	they know my invention, so they would -- I	14:30:49
14	would rely on their understanding of the	14:30:54
15	legal requirements.	14:30:55
16	BY MR. LIU:	14:31:04
17	Q. I'm purely talking about what is actually	14:31:04
18	included in your declaration, the declaration	14:31:06
19	that you signed on December 21st, 2023.	14:31:09
20	At the time -- my question for you	14:31:14
21	is: At the time of signing this declaration	14:31:17
22	on December 21st, 2003, did you have an	14:31:19

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1	understanding of the legal requirements for	14:31:22
2	inventorship?	14:31:24
3	MS. PHENG: Same objections.	14:31:25
4	THE WITNESS: Well, I -- as I said	14:31:30
5	earlier, I -- if I had the legal requirements	14:31:32
6	in front of me, I could read it out. But	14:31:37
7	since I don't have them, I have to say I	14:31:39
8	don't have it. So I don't have a legal	14:31:41
9	understanding.	14:31:43
10	BY MR. LIU:	14:31:51
11	Q. Okay. I think we're getting a little	14:31:51
12	confused. I'm going to read back my question	14:31:54
13	again. My question is only talking about the	14:31:57
14	declaration that you signed on December 21st,	14:31:59
15	2023.	14:32:02
16	A. Right.	14:32:02
17	Q. Did you have an understanding of the legal	14:32:02
18	requirements for inventorship when you signed	14:32:06
19	this declaration in December of 2023?	14:32:09
20	MS. PHENG: Same objections.	14:32:13
21	THE WITNESS: Let me rephrase	14:32:15
22	that. So I stand by what is in the	14:32:16

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1	declaration, right?	14:32:19
2	MR. LIU: Okay.	14:32:22
3	THE WITNESS: Now, I think your	14:32:22
4	question is a little different.	14:32:23
5	MR. LIU: Yes.	14:32:25
6	THE WITNESS: It is not about the	14:32:26
7	declaration, right? It is about	14:32:27
8	inventorship.	14:32:29
9	BY MR. LIU:	14:32:30
10	Q. Yes. And what I'm asking you is: When you	14:32:30
11	used the word "invent" or "invented" in your	14:32:33
12	declaration, did you have an understanding of	14:32:36
13	the legal requirements for inventorship when	14:32:40
14	you signed this declaration in December 21 of	14:32:44
15	2023?	14:32:47
16	MS. PHENG: Same objections to	14:32:49
17	scope, relevance, form and foundation.	14:32:51
18	THE WITNESS: I stand by every	14:32:53
19	word in that, in the declaration.	14:32:55
20	BY MR. LIU:	14:33:16
21	Q. Okay. On December 21st, 2023, when you	14:33:16
22	signed your declaration, what was your	14:33:19

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1	understanding of the legal requirements for	14:33:22
2	inventorship?	14:33:25
3	MS. PHENG: Same objections.	14:33:28
4	THE WITNESS: I would just say	14:33:32
5	that I stand by the declaration, and that's	14:33:33
6	all I can say.	14:33:36
7	BY MR. LIU:	14:33:38
8	Q. I'm sorry, that's -- you're not answering my	14:33:38
9	questions, Dr. Dandiker. And it's a very	14:33:42
10	simple one.	14:33:44
11	A. Okay.	14:33:45
12	Q. I'm asking if you -- oh, sorry. Let me ask	14:33:45
13	the question first.	14:33:48
14	A. Okay.	14:33:48
15	Q. You told me earlier that you did not have an	14:33:49
16	understanding of the legal requirements for	14:33:52
17	inventorship.	14:33:54
18	And I'm asking you: When you signed	14:33:55
19	your declaration on December 21st, 2023, did	14:33:57
20	you have an understanding of the legal	14:34:00
21	requirements for inventorship?	14:34:03
22	A. Let me kind of rephrase this. I've said many	14:34:05

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1	times that I stand by the declaration. You	14:34:09
2	are asking me a question, do I have a legal	14:34:12
3	understanding of inventorship. I would say	14:34:14
4	I'm not an attorney, so I don't have it.	14:34:18
5	Q. Okay. Even -- okay.	14:34:23
6	A. And I think if that is not satisfactory, then	14:34:25
7	I don't know what else I can say.	14:34:28
8	Q. So currently you do not have an understanding	14:34:30
9	of the legal requirements for inventorship,	14:34:34
10	correct?	14:34:37
11	A. I'm saying that I'm not an attorney --	14:34:38
12	MS. PHENG: Objection to form, I	14:34:38
13	think this has been asked and answered --	14:34:43
14	THE COURT REPORTER: I'm sorry --	14:34:44
15	MR. LIU: Counsel, I'm going to	14:34:45
16	ask that you keep your objections to one word	14:34:46
17	only, per PTO rules.	14:34:47
18	MS. PHENG: Objection to form.	14:34:51
19	BY MR. LIU:	14:34:52
20	Q. My question for you -- my question for you,	14:34:53
21	Dr. Dandiker, is: Currently, do you have an	14:34:53
22	understanding of the legal requirements for	14:34:55

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1	inventorship?	14:34:57
2	MS. PHENG: Objection to form.	14:34:58
3	THE WITNESS: I refuse to answer	14:34:59
4	that.	14:35:00
5	BY MR. LIU:	14:35:02
6	Q. Excuse me, this is my deposition, you have to	14:35:03
7	answer my questions. And you agreed to the	14:35:04
8	ground rules that I set forward when we	14:35:07
9	started this deposition; is that correct?	14:35:08
10	A. I don't recall.	14:35:10
11	Q. You don't recall --	14:35:12
12	A. Yeah.	14:35:13
13	Q. You don't recall when I said that you can	14:35:14
14	only refuse to answer my questions if your	14:35:16
15	counsel objects to the question as	14:35:19
16	privileged? And you agreed that you would	14:35:21
17	answer every question that I asked you,	14:35:23
18	correct?	14:35:25
19	A. So -- so --	14:35:25
20	Q. Just answer the question. Do you agree --	14:35:29
21	A. I have said several times I am not an	14:35:31
22	attorney. If you're asking me for a legal	14:35:34

1	definition, I don't have that. And if --	14:35:36
2	Q. Okay.	14:35:39
3	A. If you believe that only a legal definition	14:35:40
4	of inventorship is appropriate at this stage,	14:35:47
5	then I'm not the person to ask for that, that	14:35:51
6	would be an attorney. I'm not an attorney.	14:35:54
7	So I have to say that if that is your	14:35:56
8	objective, then I have to say that I don't	14:35:59
9	understand it, because I'm not an attorney.	14:36:03
10	Q. Okay. Thank you.	14:36:06
11	But you did not have an understanding	14:36:08
12	of the legal requirements for inventorship	14:36:11
13	when you signed your declaration in December	14:36:13
14	of 2023? You agree with me on that, right?	14:36:15
15	MS. PHENG: Counsel, objection to	14:36:18
16	form. And, again, I renew my objection to	14:36:21
17	the scope and the relevance and the	14:36:23
18	foundation to this.	14:36:24
19	I think we're getting a little bit	14:36:26
20	out of hand. Maybe we can just move on to a	14:36:28
21	different line of questioning.	14:36:31
22	MR. LIU: Counsel, please do	14:36:32

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1	not -- this is -- this is way beyond the PTO	14:36:34
2	rules.	14:36:38
3	BY MR. LIU:	14:36:39
4	Q. Dr. Dandiker, I'm going to ask my --	14:36:39
5	MS. PHENG: And under the PTO	14:36:41
6	rules, if this starts to get harassing, and	14:36:43
7	I'm a little bit worried, I'm happy to take	14:36:45
8	this off the record, but if this starts to	14:36:47
9	get harassing, then we do need to change the	14:36:49
10	line of questioning here.	14:36:51
11	MR. LIU: I understand. I am not	14:36:53
12	harassing him. I'm purely asking a question	14:36:54
13	that he's refusing to answer.	14:36:57
14	BY MR. LIU:	14:36:58
15	Q. Dr. Dandiker, this is a very, very simple	14:36:59
16	question.	14:37:01
17	Did you have an understanding of the	14:37:01
18	legal requirements for inventorship when you	14:37:03
19	signed your declaration in December 21, 2023?	14:37:06
20	Can you answer -- can you answer yes or no?	14:37:09
21	MS. PHENG: Same objections.	14:37:12
22	THE WITNESS: I stand by what is	14:37:13

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1	in the declaration.	14:37:15
2	BY MR. LIU:	14:37:16
3	Q. Again, that was not my question.	14:37:16
4	A. Yeah, so that's my answer.	14:37:17
5	Q. Please answer my question yes or no. And	14:37:22
6	I'll ask it one last time.	14:37:25
7	Did you have an understanding of the	14:37:29
8	legal requirements for inventorship when you	14:37:31
9	signed your declaration in December 21, 2023?	14:37:35
10	Yes or no?	14:37:38
11	MS. PHENG: Same objections.	14:37:39
12	Please answer the question.	14:37:45
13	THE WITNESS: Okay. I'll say no.	14:37:47
14	MR. LIU: Okay. Rachel, can we	14:37:58
15	please bring back up Exhibit 2055.	14:37:59
16	THE TECHNICIAN: I'm sorry, which	14:38:02
17	tab number was that?	14:38:22
18	MR. LIU: That's Tab 1.	14:38:23
19	THE TECHNICIAN: (Complies.)	14:38:25
20	MR. LIU: Thank you. And if we	14:38:26
21	could go to page 11 of his declaration. That	14:38:34
22	might be a different page. If you could go	14:38:38

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1	to the bottom, it should be -- yeah, page 11.	14:38:41
2	Thank you.	14:38:43
3	THE TECHNICIAN: (Complies.)	14:38:44
4	BY MR. LIU:	14:38:45
5	Q. So if we go to paragraph 25, do you see in	14:38:45
6	the second sentence you say, "Because Serono	14:38:48
7	researchers and not IVAX were working on	14:38:54
8	developing proposed dosing regimens of	14:38:56
9	cladribine for treating MS," you say, "I	14:38:59
10	believe that as part of the joint research	14:39:02
11	and development agreement, Serono	14:39:05
12	communicated the dosing regimen disclosed in	14:39:08
13	the '247 provisional and the Bodor PCT to me,	14:39:10
14	Dr. Marcus, and other members of the IVAX	14:39:15
15	team"?	14:39:17
16	Do you see that?	14:39:17
17	A. I do see that.	14:39:18
18	Q. Okay. Who at Serono communicated the dosing	14:39:19
19	regimen to you?	14:39:25
20	A. Well, I think you only have to look at the	14:39:26
21	Amsterdam minutes. It was	14:39:28
22	Dr. Bresnahan-Lopez [sic].	14:39:35

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1	Q. And what exactly was communicated to you by	14:39:39
2	Dr. Lopez-Bresnahan?	14:39:42
3	A. I think if I read it out again, you know, it	14:39:44
4	is what the proposed dosing regimen should	14:39:47
5	be.	14:39:54
6	Q. And what was the proposed dosing regimen?	14:39:54
7	MS. PHENG: Objection to form.	14:39:57
8	THE WITNESS: That's, again, not	14:39:59
9	my area of expertise, so I cannot comment.	14:40:00
10	But I do recall there were many, many	14:40:04
11	different proposals made at the time.	14:40:06
12	BY MR. LIU:	14:40:10
13	Q. So do you recall -- do you have an	14:40:11
14	understanding of what the proposed dosing	14:40:13
15	regimen was communicated to you in the	14:40:15
16	August 2003 meeting?	14:40:19
17	A. I think we'd have to go to the minutes of the	14:40:22
18	meeting to --	14:40:24
19	MS. PHENG: Objection to form.	14:40:25
20	THE WITNESS: -- to see if it's	14:40:27
21	there. I don't recall otherwise.	14:40:29
22	BY MR. LIU:	14:40:31

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1 Q. So you don't recall any specific details of
2 the proposed dosing regimen that
3 Dr. Lopez-Bresnahan communicated to you in
4 August 2003?

14:40:42

14:40:44

14:40:46

14:40:49

5 MS. PHENG: Objection to form.

14:40:51

6 THE WITNESS: Yes, that is

14:40:52

7 correct, because there were many ideas being

14:40:53

8 thrown around, and I don't know which

14:40:58

9 specific dosing regimen you are referring to.

14:41:01

10 BY MR. LIU:

14:41:06

11 Q. Who at Serono communicated the dosing regimen
12 to Dr. Marcus?

14:41:06

14:41:10

13 A. I think that's for you to ask Dr. Marcus.

14:41:13

14 Q. Do you recall the details of any dosing
15 regimen that was communicated to you?

14:41:34

14:41:38

16 MS. PHENG: Objection to form.

14:41:41

17 THE WITNESS: I don't at this

14:41:44

18 stage, no.

14:41:45

19 BY MR. LIU:

14:41:56

20 Q. Who at Serono communicated the dosing regimen
21 to the other members of the IVAX team?

14:41:57

14:42:00

22 MS. PHENG: Objection to form,

14:42:07

1	foundation.	14:42:08
2	THE WITNESS: I would not know	14:42:11
3	other than, you know, it could be any one of	14:42:13
4	those individuals on those minutes.	14:42:17
5	BY MR. LIU:	14:42:22
6	Q. So you wouldn't know what dosing regimen was	14:42:25
7	actually communicated to the other members of	14:42:27
8	the IVAX team, correct?	14:42:29
9	A. That is correct. And again, you know, just	14:42:30
10	to kind of clarify, in terms of drug	14:42:34
11	development, it is not a static process.	14:42:37
12	What is communicated at one moment in time	14:42:41
13	changes as time goes along as we know more.	14:42:44
14	So it's never kind of static.	14:42:47
15	And then, you know, people are	14:42:50
16	speaking to a lot of different people, so you	14:42:54
17	just don't know who is speaking to who and	14:42:56
18	what is being said.	14:42:58
19	But in my particular case, this is	14:43:00
20	not my area of expertise, so I wouldn't	14:43:02
21	really, you know, be involved.	14:43:05
22	Q. Okay.	14:43:09

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1	MR. LIU: If we could go to the	14:43:11
2	next page on paragraph 27.	14:43:14
3	THE TECHNICIAN: (Complies.)	14:43:16
4	BY MR. LIU:	14:43:18
5	Q. You state in this paragraph, "I believe that	14:43:18
6	the Serono team communicated additional	14:43:21
7	details about their dosing regimen to me and	14:43:24
8	the rest of the IVAX team in addition" -- "in	14:43:27
9	additional other meetings and emails before	14:43:31
10	February 20" -- "2004."	14:43:34
11	Do you see that?	14:43:36
12	A. Yes, I do see that.	14:43:37
13	Q. And what additional details are we referring	14:43:39
14	to?	14:43:42
15	A. As I had mentioned earlier, that there were	14:43:43
16	many dosing regimens being discussed at that	14:43:45
17	time. So, you know, whether people should	14:43:48
18	have, you know, tablets for 1 month or 2	14:43:55
19	months or 3 months or 4 months or 6 months or	14:43:58
20	12 months, so they were all being discussed.	14:44:03
21	So, you know, nothing was fixed at that time.	14:44:06
22	But, certainly, many, many discussions were	14:44:09

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1	ongoing.	14:44:13
2	And the only reason where this	14:44:16
3	becomes important for me in particular was,	14:44:20
4	you know, one of my actions, as you saw from	14:44:23
5	the previous minutes, was to supply the	14:44:27
6	tablets. So without knowing, you know, how	14:44:29
7	many to supply, you wouldn't know.	14:44:31
8	So but there were many, many kind of	14:44:33
9	different regimens being discussed at that	14:44:40
10	time.	14:44:43
11	Q. And you talk about Serono communicating these	14:44:45
12	details in other meetings and emails before	14:44:50
13	February 2004.	14:44:54
14	Do you see that?	14:44:55
15	A. Yes.	14:44:56
16	Q. And what emails are you referring to here?	14:44:56
17	A. So these are emails between Serono and IVAX.	14:45:00
18	So, you know, that meeting was not in	14:45:05
19	isolation, and also events after the meeting	14:45:10
20	were not in isolation. So there was always	14:45:13
21	communication, you know, via emails and on	14:45:16
22	the phone with various people. So it's an	14:45:22

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1	ongoing process.	14:45:24
2	Q. And when was the last time you saw these	14:45:26
3	emails?	14:45:28
4	A. It must have been before I left, 2004.	14:45:29
5	MR. LIU: Okay. Let's take a	14:45:48
6	break.	14:45:50
7	THE VIDEOGRAPHER: Okay. We are	14:45:51
8	going off the record. The time is 2:46.	14:45:52
9	(Recess.)	14:45:57
10	THE VIDEOGRAPHER: We are back on	14:54:04
11	the record. The time is 2:54.	14:54:06
12	BY MR. LIU:	14:54:11
13	Q. Dr. Dandiker, did you discuss the substance	14:54:11
14	of your testimony with counsel on your break?	14:54:13
15	A. No.	14:54:16
16	MS. BOND: I do want to mention on	14:54:19
17	the record, I did just see, like, one minute	14:54:21
18	outside of the room with the phone. No	14:54:24
19	accusations or anything, I was just going to	14:54:25
20	mention that.	14:54:27
21	BY MR. LIU:	14:54:30
22	Q. Dr. Dandiker, did you access your phone to --	14:54:30

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1	did you access any documents or files on your	14:54:34
2	phone --	14:54:36
3	A. No.	14:54:36
4	Q. -- relating to the substance of your	14:54:36
5	testimony today?	14:54:38
6	A. No. I had a text from my daughter, and it's	14:54:38
7	always important not to ignore it.	14:54:43
8	MR. LIU: No further questions for	14:54:48
9	you, Dr. Dandiker. Thank you.	14:54:49
10	MS. PHENG: Tyler, are you passing	14:54:56
11	the witness?	14:54:57
12	MR. LIU: Yes, I'm passing the	14:54:58
13	witness.	14:54:59
14	MS. PHENG: Okay.	14:54:59
15		14:54:59
16	EXAMINATION	14:55:00
17	BY MS. PHENG:	14:55:00
18	Q. I just have one or two quick questions,	14:55:01
19	Dr. Dandiker.	14:55:04
20	Earlier you had said that you didn't	14:55:06
21	recall the specific details of some of the	14:55:09
22	dosing regimens that Serono had disclosed.	14:55:12

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1	If you wanted to find those details today,	14:55:15
2	what would you look at to refresh your	14:55:18
3	memory?	14:55:21
4	A. So I think I'd go back to the declaration,	14:55:21
5	and then within that, I think there's a	14:55:27
6	reference to the minutes of the Amsterdam	14:55:32
7	meeting, and within that, I think on one of	14:55:39
8	the pages there are details. But I would	14:55:42
9	have to go back to really look at that to	14:55:46
10	refresh my memory.	14:55:50
11	Q. And besides the Amsterdam meeting minutes,	14:55:53
12	are there any other documents that you would	14:55:56
13	go back to look at to refresh your memory?	14:55:58
14	A. I don't have any access to any other	14:56:00
15	documents other than what has been provided	14:56:03
16	to me prior to this deposition.	14:56:05
17	Q. And then to the best of your recollection, do	14:56:09
18	the minutes of the Amsterdam meeting minutes	14:56:12
19	accurately summarize some of the regimens	14:56:16
20	that Serono had disclosed to you?	14:56:19
21	A. I believe so.	14:56:21
22	MS. PHENG: No further questions	14:56:24

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1	for me.	14:56:25
2	THE VIDEOGRAPHER: All right. Is	14:56:31
3	there anything else for the record?	14:56:32
4	MR. LIU: Sorry, I just -- can I	14:56:35
5	take a break? I'll be right back.	14:56:36
6	THE WITNESS: Sure.	14:56:39
7	MR. LIU: Give us five minutes.	14:56:40
8	THE VIDEOGRAPHER: Okay. Sure.	14:56:40
9	We are going off the record. The time is	14:56:41
10	2:56.	14:56:43
11	(Recess.)	14:56:44
12	THE VIDEOGRAPHER: We are back on	15:00:12
13	the record. The time is 3 o'clock.	15:00:16
14	MR. LIU: Dr. Dandiker, we have no	15:00:20
15	further questions. Thank you for your time.	15:00:22
16	THE WITNESS: Okay. Thank you.	15:00:24
17	MS. PHENG: While we're on the	15:00:25
18	record, I'd just like to designate this	15:00:27
19	provisionally as confidential under the	15:00:29
20	protective order.	15:00:31
21	MR. LIU: Okay.	15:00:34
22	MS. PHENG: And also, Amy, if you	15:00:34

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1	need us to order the transcript on the	15:00:35
2	record, I'm happy to.	15:00:42
3	THE COURT REPORTER: Yes, if we	15:00:42
4	could get transcript orders, please.	15:00:43
5	MR. LIU: Sure. I mean, we would	15:00:43
6	like a rough today, and expedite the full	15:00:44
7	transcript hopefully early next week, if	15:00:52
8	that's possible.	15:00:53
9	THE COURT REPORTER: Okay.	15:00:54
10	MS. PHENG: And we'll take the	15:00:54
11	same.	15:00:56
12	THE COURT REPORTER: Thank you.	15:00:58
13	THE VIDEOGRAPHER: If there's	15:00:58
14	nothing else, then this marks the end of the	15:00:59
15	videotaped deposition of Dr. Yogesh Dandiker,	15:01:01
16	and we are going off the record at 3:00 p.m.	15:01:04
17	(Deposition concluded at	15:01:07
18	3:00 p.m.)	
19		
20		
21		
22		

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1 CERTIFICATE OF SHORTHAND REPORTER-NOTARY PUBLIC

2 I, Amy L. Larson, Registered Professional
3 Reporter, Certified Shorthand Reporter, Certified
4 Court Reporter, and Notary Public within and for
5 the State of Minnesota, do hereby certify:

6 That YOGESH DANDIKER, Ph.D., the witness
7 whose deposition is hereinbefore set forth, was
8 duly sworn by me before the commencement of such
9 deposition and that such deposition was taken
10 before me and is a true record of the testimony
11 given by such witness.

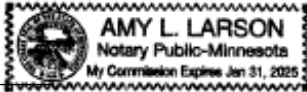
12 I further certify that the adverse party,
13 MERCK SERONO S.A was represented by counsel
14 at the deposition.

15 I further certify that the deposition of
16 YOGESH DANDIKER, Ph.D., occurred at the offices
17 of Fabyanske, Westra, Hart & Thomson, P.A.,
18 333 South Seventh Street, Suite 2600, Minneapolis,
19 Minnesota, on Friday, February 16, 2024,
20 commencing at 9:41 a.m. to 3:00 p.m.

21 I further certify that I am not related to
22 any of the parties to this action by blood or

1 marriage, I am not employed by or an attorney to
2 any of the parties to this action, and that I am
3 in no way interested, financially or otherwise, in
4 the outcome of this matter.

5
6
7 IN WITNESS WHEREOF, I have hereunto set my
8 hand this 18th day of February, 2024.

9
10 Amy L. Larson 

11 Amy L. Larson, RPR, CCR, CSR

12 My commission expires January 31, 2025
13
14
15
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17
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22